EPA Reg. Jacket 86854-1 vol 1

Ultra-Lyte®

Aqueous Solution of Sodium Chloride

Ultra-Lyte® solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

ACCEPTED
02/28/2017
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 86854-1

Manufactured by:
Clarentis Technologies, LLC
22 St. James Drive, Palm Beach Gardens, FL 33418
Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1

EPA Est. # 86854-FL-001

Ultra-Lyte® must be used within 30 days after being produced *OR product must be tested with chlorine test kit provided by* Clarentis Technologies, LLC. *DO NOT USE PRODUCT when Chlorine concentration is below 450ppm.*

Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

**This product is not meant to be used as a terminal sterilant/ high level disinfectant on any surface or instrument that 1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the bold barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

FIRST AID	
If in Eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical hazards

Ultra-Lyte® is not compatible with other chemicals such as acids and hydrogen peroxide. **Ultra-Lyte®** is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte®** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte®** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte®** can be applied as a liquid or spray.

Ultra-Lyte® freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte®** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte® product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

****Hard, Non-Porous Surface Disinfection**

To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte® at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects
+ Cleans and disinfects hard, non-porous surfaces + Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7

+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)

+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic
(mold and mildew), and algae.
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water. Apply Ultra-Lyte® (full strength) at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats

Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens

Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks

Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte® with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte® into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte® at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte® into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F).

Pesticide Disposal: Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with hypochlorous acid only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Create/E... Collections Utilities Query T... Portal Help Exit

S: 998078 Milesto mail:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 86854 CLARENTIS TECHNOLOGIES, LLC

Resubmission: Yes No

Fee For Service: Yes No

Billable: Yes No

Print Letter

Enter More Information

Tracking

Risk Manager: Antimicrobials Division, Risk Management Team 32

Product #: 86854-1 Product Name: ULTRA-LYTE

Override#:

Me Too Section3: 82341-1 Me Too Product Name: ECAFLO ANOLYTE

Application Date: 23-Jan-2017 OPP Rec'vd Date: 25-Jan-2017

Front End Date: 25-Jan-2017 Risk Manager Send Date: 25-Jan-2017

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Receipt Content | Des

Paper Label

View/Edit

Fast Track: New Ingredient:

Receipt Description:

LABEL AMENDMENT

New Ingredient Request Date:

New Ingredient Received Date:

Form A: Signature Date: Form B: Signature Date:

MB

526648

Please read instructions on reverse before completing form. Form Approved OMB No. 2070-0060

Print Form

United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☒ Amendment ☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Clarentis Technologies LLC / 86854-1	Demson Fuller	☒ None ☐ Restricted
4. Company/Product (Name)	**PM#**	
Clarentis Technologies LLC / Ultra-Lyte	32	

5. Name and Address of Applicant *(Include ZIP Code)*

Clarentis Technologies LLC
22 St. James Drive,
Palm Beach Gardens, FL 33418

☐ *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☒ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated _____

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated _____

☐ "Me Too" Application.

☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information ☒ Label ☐ Container

4. Size(s) Retail Container 1qt, 1, 5, 55, 275 gallons

5. Location of Label Directions ☒ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☒ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin R Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
	Agent
4. Typed Name	**5. Date**
Kevin R Kutcel	1-21-17

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 25, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

KEVIN KUTCEL
KRK CONSULTING LLC
CLARENTIS TECHNOLOGIES, LLC
5807 CHURCHILL WAY
MEDINA, OH 44256-

PRODUCT NAME: ULTRA-LYTE
COMPANY NAME: CLARENTIS TECHNOLOGIES, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 86854-1
EPA RECEIPT DATE: 01/25/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 32, at (703) 308-8062.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {998078Z~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 32

Receipt No. S- 998078

EPA File Symbol/Reg. No. 86854-1

Pin-Punch Date: 1/25/2017

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: W. Hanson (Team 1) Date: 1-25-17

Remarks: 302 Label Amendment

KRK Consulting LLC

5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

January 21, 2017

US EPA (AMEND)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: FAST TRACK AMENDMENT
Product: Ultra-Lyte
EPA Reg. No.86854-1
Revised Storage and Disposal

Please accept the highlighted label and 3 copies of the proposed final label for product "Ultra-Lyte" (EPA Reg. No. 86854-1) in which the storage and disposal has been amended to more accurately describe the storage conditions of the product and also to add industrial and commercial use packages.

Attached is EPA Form 8570-1 regarding this amendment. This amendment is consistent with the requirements of EPA's regulations at 40 CFR 156.46, 156.140, 156.144, 156,146 and 156.156 and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand this it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for Clarentis Technologies LLC and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for Clarentis Technologies LLC

HIGHLIGHTED

Ultra-Lyte®

Aqueous Solution of Sodium Chloride

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- are disinfecting solutions,
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- are produced in a simple process by an electrolytic cell,
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CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis Technologies, LLC
22 St. James Drive, Palm Beach Gardens, FL 33418
Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1 EPA Est. # 86854-FL-001

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PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical hazards

Ultra-Lyte® is not compatible with other chemicals such as acids and hydrogen peroxide. **Ultra-Lyte®** is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte®** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte®** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte®** can be applied as a liquid or spray.

Ultra-Lyte® freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte®** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte® product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

****Hard, Non-Porous Surface Disinfection**
To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte® at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects
+ Cleans and disinfects hard, non-porous surfaces + Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa

+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)

+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic
(mold and mildew), and algae.
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water. Apply Ultra-Lyte® (full strength) at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats

Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens

Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks

Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte® with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte® into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte® at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte® into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F).

Pesticide Disposal: Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with hypochlorous acid only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Ultra-Lyte®

Aqueous Solution of Sodium Chloride

Ultra-Lyte® solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:	
Hypochlorous Acid	0.046%
OTHER INGREDIENTS:	99.954%
TOTAL:	100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis Technologies, LLC
22 St. James Drive, Palm Beach Gardens, FL 33418
Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1 EPA Est. # 86854-FL-001

Ultra-Lyte® must be used within 30 days after being produced *OR product must be tested with chlorine test kit provided by* Clarentis Technologies, LLC. *DO NOT USE PRODUCT when Chlorine concentration is below 450ppm.*

Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

**This product is not meant to be used as a terminal sterilant/ high level disinfectant on any surface or instrument that 1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the bold barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

FIRST AID	
If in Eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical hazards

Ultra-Lyte® is not compatible with other chemicals such as acids and hydrogen peroxide. **Ultra-Lyte®** is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte®** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte®** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte®** can be applied as a liquid or spray.

Ultra-Lyte® freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte®** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte® product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

****Hard, Non-Porous Surface Disinfection**
To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte® at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects
+ Cleans and disinfects hard, non-porous surfaces + Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7

+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)

+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic
(mold and mildew), and algae.
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
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Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
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Medical Clinics
Medical Facilities
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Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
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Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

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Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
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Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

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Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats

Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens

Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks

Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte® with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte® into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte® at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte® into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F).

Pesticide Disposal: Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with hypochlorous acid only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Ultra-Lyte®

Aqueous Solution of Sodium Chloride

Ultra-Lyte® solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis Technologies, LLC
22 St. James Drive, Palm Beach Gardens, FL 33418
Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1 EPA Est. # 86854-FL-001

Ultra-Lyte® must be used within 30 days after being produced *OR product must be tested with chlorine test kit provided by* Clarentis Technologies, LLC. *DO NOT USE PRODUCT when Chlorine concentration is below 450ppm.*

Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

**This product is not meant to be used as a terminal sterilant/ high level disinfectant on any surface or instrument that 1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the bold barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

FIRST AID	
If in Eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical hazards

Ultra-Lyte® is not compatible with other chemicals such as acids and hydrogen peroxide. **Ultra-Lyte®** is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte®** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte®** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte®** can be applied as a liquid or spray.

Ultra-Lyte® freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte®** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte® product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

****Hard, Non-Porous Surface Disinfection**
To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte® at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects
+ Cleans and disinfects hard, non-porous surfaces + Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7

+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)

+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic
(mold and mildew), and algae.
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water. Apply Ultra-Lyte® (full strength) at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats

Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens

Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks

Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte® with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte® into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte® at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte® into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F).

Pesticide Disposal: Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with hypochlorous acid only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Ultra-Lyte®

Aqueous Solution of Sodium Chloride

Ultra-Lyte® solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis Technologies, LLC
22 St. James Drive, Palm Beach Gardens, FL 33418
Tel: (561) 799-9299, info@clarentis.com

EPA Reg. # 86854-1 EPA Est. # 86854-FL-001

Ultra-Lyte® must be used within 30 days after being produced *OR product must be tested with chlorine test kit provided by* Clarentis Technologies, LLC. *DO NOT USE PRODUCT when Chlorine concentration is below 450ppm.*

Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

**This product is not meant to be used as a terminal sterilant/ high level disinfectant on any surface or instrument that 1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the bold barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

FIRST AID	
If in Eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes for 15-20 minutes. Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye.
Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.	

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing or using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Physical or Chemical hazards

Ultra-Lyte® is not compatible with other chemicals such as acids and hydrogen peroxide. **Ultra-Lyte®** is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte®** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte®** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte®** can be applied as a liquid or spray.

Ultra-Lyte® freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte®** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte® product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

****Hard, Non-Porous Surface Disinfection**
To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte® at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects
+ Cleans and disinfects hard, non-porous surfaces + Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7

+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)

+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Inhibits the growth of odor causing bacteria, bacteria which cause staining and discoloration, mildewstatic
(mold and mildew), and algae.
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water. Apply Ultra-Lyte® (full strength) at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats

Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens

Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks

Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte® with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte® into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte® at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte® with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte® into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

For Household/residential use packages:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F) and above 0°C (32°F).

Pesticide Disposal: Non-refillable container. Do not reuse or refill this container. Wrap container and put in trash or offer for recycling if available.

For industrial and commercial use packages:

Small Packages (1 gallon or less):

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: Non-refillable container. Do not reuse or refill this container. Triple rinse container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

Pails, Drums and IBCs:

Pesticide Storage: Store in original, tightly closed container in an area inaccessible to children or persons unfamiliar with its use and away from food or feed. Keep tightly closed until ready to use. Reclose tightly after each use. Store in original, unopened containers at or below 25 C (77F).

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling: REFILLABLE CONTAINER. Refill this container with hypochlorous acid only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 14, 2017

Kevin Kutcel
Agent for Clarentis Technologies LLC
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256

Subject: Notification per PRN 98-10 –Alternate Brand Name
Product Name: Ultra-Lyte
EPA Registration Number: 86854-1
Application Date: January 23, 2017
Decision Number: 525518

Dear Mr. Kutcel:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The alternate brand name "Petrolyte" has been added to the product record.

If you have any questions, you may contact Donna Kamarei at (703)347-0443 or via email at Kamarei.donna@epa.gov.

Sincerely,

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

KRK Consulting LLC

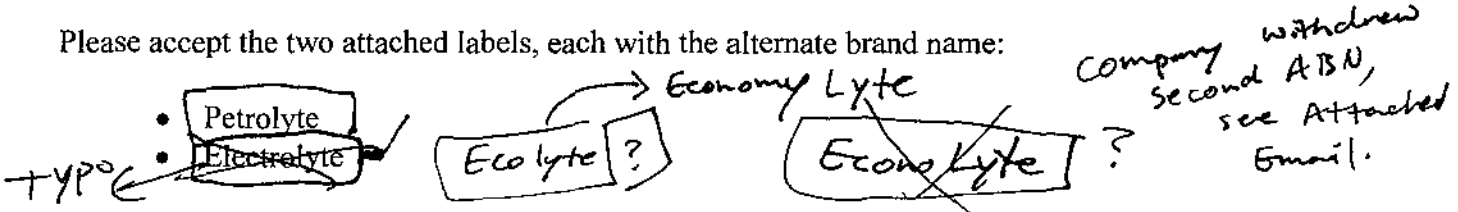
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
E-mail: kevinkutcel@gmail.com

January 21, 2017

US EPA (NOTIF)
Office of Pesticide Programs
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: PR Notice 1998-10 Notification (EPA No.86854-1)
Alternate Brand Names

Please accept the two attached labels, each with the alternate brand name:



Attached is EPA Form 8570-1 regarding this notification as required in PR Notice 1998-10. This notification is consistent with the guidance in PR Notice 1998-10 and the requirements of EPA's regulations at 40 CFR 156.46, 156.140, 156.144, 156,146 and 156.156 and no other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand this it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of PR Notice 98-10 and CFR 156.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please note that KRK Consulting LLC is the authorized agent handling all correspondence for Clarentis Technologies LLC and therefore all responses should be directed to the contact information on the letterhead above.

Best Regards,

Kevin R. Kutcel,
Agent for Clarentis Technologies LLC

Please read instructions on reverse before com ng form. Form Approved. B No. 2070-0060 Print Form

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [ ] Amendment
- [x] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
Clarentis Technologies LLC / 86854-1	Demson Fuller	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Clarentis Technologies LLC / Ultra-Lyte	32	

5. Name and Address of Applicant *(Include ZIP Code)*

Clarentis Technologies LLC
22 St. James Drive,
Palm Beach Gardens, FL 33418

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [x] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Please see cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1, 55, 275 gal	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

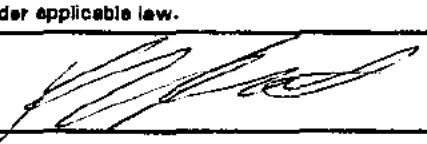
1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Kevin R Kutcel	Agent	440-263-7305

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6 Date Application Received (Stamped)

2. Signature	3. Title
	Agent
4. Typed Name	**5. Date**
Kevin R Kutcel	1-21-17

From: Kevin Kutcel
To: Kamarei, Donna
Cc: Fuller, Demson
Subject: RE: Follow-up needed for EPA action 86854-1
Date: Tuesday, February 14, 2017 12:52:32 PM

Donna,

I spoke with the registrant and they have no interest in the ABN Econlyte (remember it was my idea), so they have decided just to proceed with the ABN Petrolyte. Please send me an approval letter for Petrolyte.

Warm Regards,

Kevin Kutcel
KRK Consulting LLC
5807 Churchill Way
Medina, OH 44256
Tel: 440-263-7305
Fax: 440-398-0476
E-mail: kevinkutcel@gmail.com

From: Kamarei, Donna [mailto:Kamarei.Donna@epa.gov]
Sent: Tuesday, February 14, 2017 12:16 PM
To: Kevin Kutcel
Cc: Fuller, Demson
Subject: RE: Follow-up needed for EPA action 86854-1

Hi Kevin,

I just spoke with Demson regarding the ABN.
EconLyte would be more appropriate than EcoLyte.
If that's the direction the company would like to go, please email me a new cover letter and I'll work on completing this action for you ASAP!

Thanks,
Donna

From: Kamarei, Donna

Sent: Monday, February 13, 2017 3:31 PM
To: 'Kevin Kutcel' <kevinkutcel@gmail.com>
Cc: Fuller, Demson <Fuller.Demson@epa.gov>
Subject: Follow-up needed for EPA action 86854-1

Hi Kevin,

It was good speaking with you earlier.
Please provide clarification on the suggested ABNs for EPA Reg No 86854-1.

Many thanks,
Donna

Donna Kamarei
Chemical Review Manager
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 347-0443

Material to be added to an e-Jacket/Jacket

Reg. No. 85854-1

Description: _____

_____

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top = newest)**
   - ☐ **File Location: (PDF page number, i.e., "before page 45")**

     _____

     _____

2. ☒ **Send to Data Extraction contractors this material:**
   - ☒ **Newly stamped accepted label**
   - ☐ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Wanda Henson

Phone: _____ **Division:** AD

Date: 2/2/2011

Created August 14, 2008

RISK ASSIGNMENT FORM

Antim ibial Division/Regulatory Managem Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Wanda Henson	**RMB** _II_ **TEAM** __34__
Description of Action:	**EPA File Symbol/Reg No.** 86854-1

Decision No. 444650	**Submission No.** 889550	**Fee for Service Action Code:**
FQPA Action Code: 302	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT: $**

	MONTH	DAY	YEAR
APPLICATION DATE	1	6	2010
EPA PIN DATE	1	6	2010
DATE PM RECEIVED FROM FRONT END	1	6	2010
Date sent to Reviewer			**2010**
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY**

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure/ Residue

COMMENTS:

ATTACHMENTS: ☑-LABELING ☐-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID:	**RESPONSE CODE:** 1162 **RESPONSE DATE:** FEB - 2 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB - 2 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

FILE COPY

Robert Brennis
Brennis Consulting Services, Inc.
6628 Birchleigh Way
Alexandria, VA 22315

Subject: Clarentis LLC
Ultra-Lyte
EPA Reg. No.: 86854-1
Application Dated: January 5, 2011
Receipt Dated: January 6, 2011

Dear Mr. Brennis:

The labeling for the product referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions.

Proposed Amendment

•To remove the restriction for generation of Ultra-Lyte on site.

Conditions

1. Revise the Precautionary statement to read "Cause moderate eye irritation. Avoid contact with eyes or clothing. Wear protective eyewear and goggles when dispensing and using this product. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."

2. Products that imply use as a general disinfectant on medical devices or medical equipment surfaces must include the PR Notice 94-4 language below and be qualified with a double asterisk, which connects it to the use site on the label for this product.

> **This product is not to be used as a terminal sterilant/high level disinfectant on any surface of instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the bold barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization of high level disinfection.

General Comments:

A stamped copy of the accepted labeling with conditions is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

Wanda Y. Henson
Acting Product Manager – Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Ultra-Lyte™

Aqueous Solution of Sodium Chloride

Ultra-Lyte™ solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA 98528
Ph: 866-363-7930 Email: info@ultra-lyte.com

EPA Reg. # 086854-1 EPA Est. # 086854-WA-001

Ultra-Lyte™ must be used within 30 days after being produced. Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

Physical or Chemical hazards

Ultra-Lyte is not compatible with other chemicals such as acids and hydrogen peroxide.

Ultra-Lyte™ is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte™** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte™** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte™** can be applied as a liquid or spray.

Ultra-Lyte™ freezes at 32° F and boils at 212° F. The anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte™** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The Ultra-Lyte product must be used within 30 days of production.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157:H7, Listeria Monocytogenes, Pseudomonas aeruginosa.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Hard, Non-Porous Surface Disinfection

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection

To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte™ at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal

+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects + Cleans and disinfects hard, non-porous surfaces
+ Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157:H7, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157:H7
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)
+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination between treated hard non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal + The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination between treated hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces+ Use where control of the hazards of cross-contamination between treated surfaces is of Prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use

+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers

Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.
Apply Ultra-Lyte™ (full strength) at 500 ppm FAC (Saturate surfaces with solution for 10 minutes. Immerse all
halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with potable water after application of disinfectant)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes
Blood Banks
Boats
Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines associated with oil & gas production
Preschool Facilities
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles

Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens
Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs

Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks
Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte™ with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte™ into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of produced water to 10.5 ppm FAC, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte™ at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte™ into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

PESTICIDE STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store in a closed dark plastic container away from direct sunlight. Store container in a cool dry area

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: Non-refillable Container. Do not refill or reuse container. Triple rinse container after emptying. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times, then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

Fw: Clarentis LLC Registration - EPA Reg. No. 86854-1

Mark Hartman to: Wanda Henson 01/06/2011 06:46 AM

Hi Wanda:

Please take care of this. I assume we can consider the email the application for amendment and stamp a new label rather than what Bob suggests. If you are swamped have Glen or David take care of it. I would like it done in two weeks if at all possible since PSB should never had included the on-site business in the first place. If that is going to be a problem given workload considerations let me know and I can try to shuffle some stuff around. Thanks.

Mark

Mark A. Hartman
Chief, Regulatory Management Branch II
Antimicrobials Division
Office of Pesticide Programs
(703) 308-0734

----- Forwarded by Mark Hartman/DC/USEPA/US on 01/06/2011 06:41 AM -----

Personal privacy information

From:	"Bob Brennis" <bob@brennis.com>
To:	Mark Hartman/DC/USEPA/US@EPA
Cc:	Dennis Edwards/DC/USEPA/US@EPA, "'Duke van Kalken'" [redacted] ShaRon Carlisle/DC/USEPA/US@EPA
Date:	01/05/2011 02:56 PM
Subject:	RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Mark -

Attached is the label with all of the required changes, minus the one that required us to produce the product on-site. We would appreciate it if the Agency could remove the previous registration from the PPLS system and reissue it with this label. Since this is a correction to the original registration, it seems appropriate to merely reissue the registration and not file a label amendment. Again, my client has been restricted from the marketplace for one-and-one-half months already and we would appreciate a rapid correction to this issue.

Let me know if you need anything else to finalize these changes.

Bob Brennis
Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
Office: 703-922-6677
Cell: [redacted]

Personal privacy information

-----Original Message-----
From: Hartman.Mark@epamail.epa.gov [mailto:Hartman.Mark@epamail.epa.gov]
Sent: Wednesday, January 05, 2011 12:06 PM
To: Bob Brennis
Cc: Edwards.Dennis@epamail.epa.gov; 'Duke van Kalken';
Mitchell.Emily@epamail.epa.gov; Carlisle.Sharon@epamail.epa.gov;

Henson.Wanda@epamail.epa.gov; Laniyan.Ibrahim@epamail.epa.gov;
Blackburn.Tajah@epamail.epa.gov
Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Bob:

Per your request, I have reviewed the information provided as well as the label and data reviews related to the Clarentis LLC Registration - EPA Reg. No. 86854-1 as well as the label and associated materials for the me-too'ed product 82341-1. The primary issue you raised on behalf of your client was the language in item #5 on the registration notice where Clarentis was required to add the statement "Ultra-Lyte must be produced on-site....". You pointed out that your client could be placed at a significant disadvantage in the marketplace when competing against similar products, including 82341-1, that do not have this label restriction.

The language used on both labels was essentially identical prior to the issuance of the registration and associated conditions. The Agency is willing to remove the condition for on-site production as a requirement. However, based on the available data, the Agency will require a production date and the clear indication on the label that the product can only be used within 30 days of the production date in order to be efficacious. Any product remaining in a container after the 30 days has expired must be disposed of in accordance with label directions.

Please submit an amendment asap that includes the other changes required by the registration letter only and we will process it expeditiously.

Mark

Mark A. Hartman
Chief, Regulatory Management Branch II
Antimicrobials Division
Office of Pesticide Programs
(703) 308-0734

From: "Bob Brennis" <bob@brennis.com> *Personal privacy information*

To: Wanda Henson/DC/USEPA/US@EPA

Cc: Dennis Edwards/DC/USEPA/US@EPA, "'Duke van Kalken'" [redacted] Mark Hartman/DC/USEPA/US@EPA, ShaRon Carlisle/DC/USEPA/US@EPA, Emily Mitchell/DC/USEPA/US@EPA

Date: 12/28/2010 11:16 AM

Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Ms. Henson -

Thanks for your response. My understanding was that you were going to present this issue at the weekly regulatory meeting a couple of weeks ago. Did that occur? I am assuming from your response that this is still an unresolved issue. I will follow up and determine our best next steps.

Bob Brennis
Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
Office: 703-922-6677
Cell: [redacted]

Personal privacy information

-----Original Message-----
From: Henson.Wanda@epamail.epa.gov [mailto:Henson.Wanda@epamail.epa.gov]

Sent: Tuesday, December 28, 2010 8:32 AM
To: Bob Brennis
Cc: 'Bob Brennis'; Edwards.Dennis@epamail.epa.gov; 'Duke van Kalken'; Hartman.Mark@epamail.epa.gov; Carlisle.Sharon@epamail.epa.gov; Mitchell.Emily@epamail.epa.gov
Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Good Morning,

If I remember correctly we had a discussion with regards to this matter, to wit, I explained that this issue would have to handled on a Managerial level. Since, the Product Science Branch made the determination, perhaps you should engage in a dialogue with the reviewer and the Branch Chief. I am willing to set up a meeting with You, the efficacy personnel and my Branch Chief, if it will help to resolve the issues.

Let me know how you intend to proceed with regards to this matter.

Sincerely,

Wanda Y. Henson
Environmental Protection Specialist
Regulatory Management Branch II
Antimicrobials Division (7510P)
(703) 308-6345

From: "Bob Brennis" <bob@brennis.com>

To: "'Bob Brennis'" <bob@brennis.com>, Wanda Henson/DC/USEPA/US@EPA

Cc: Mark Hartman/DC/USEPA/US@EPA, "'Duke van Kalken'" [redacted] Dennis Edwards/DC/USEPA/US@EPA, ShaRon Carlisle/DC/USEPA/US@EPA

Personal privacy information

Date: 12/27/2010 04:38 PM

Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Wanda and Mark -

I haven't heard a word from EPA regarding the registration issue for the product identified above. It would help if you could at least acknowledge that you are reviewing these materials and eventually allow my client the ability to distribute their product which was registered on November 17.

If Wanda is out, I would appreciate it if Mark can drop me a line. My client is very concerned and he does not understand why we have been unable to even get a return call or email message. I spoke with Dennis about this issue, but no one else has responded.

Thank you in advance for your reponse.

Bob Brennis

Brennis Consulting Services LLC

6628 Birchleigh Way

Alexandria, VA 22315

Office: 703-922-6677

Cell: [redacted]

Personal privacy information

From: Bob Brennis [mailto:bob@brennis.com]
Sent: Tuesday, December 14, 2010 9:47 AM
To: 'Henson.Wanda@epamail.epa.gov'
Cc: hartman.mark@epa.gov; 'Duke van Kalken'; 'edwards.dennis@epa.gov'; 'carlisle.sharon@epa.gov'
Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Ms. Henson -

I have not gotten a response from you concerning the request I had made

to allow the Clarentis product to be distributed. Please respond to at least allow me to know how things are going. We are very anxious to correct this issue.

Thank you in advance for your consideration.

Bob Brennis

Brennis Consulting Services LLC

6628 Birchleigh Way

Alexandria, VA 22315

Office: 703-922-6677

Personal privacy information

Cell: [redacted]

From: Bob Brennis [mailto:bob@brennis.com]
Sent: Thursday, December 09, 2010 5:35 PM
To: 'Bob Brennis'; 'Henson.Wanda@epamail.epa.gov'
Cc: hartman.mark@epa.gov; 'Duke van Kalken'; 'edwards.dennis@epa.gov'; 'carlisle.sharon@epa.gov'
Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Ms. Henson -

I understood that you were planning on discussing this at the Tuesday registration meeting, so I am simply contacting you to find out if there has been any decision on this issue. Please get back to me with any information as soon as possible.

Bob Brennis

Brennis Consulting Services LLC

6628 Birchleigh Way

Alexandria, VA 22315

Office: 703-922-6677

Personal privacy information

Cell: [redacted]

From: Bob Brennis [mailto:bob@brennis.com]
Sent: Thursday, December 02, 2010 3:13 PM
To: 'Henson.Wanda@epamail.epa.gov'
Cc: hartman.mark@epa.gov; 'Duke van Kalken'; 'edwards.dennis@epa.gov'; 'carlisle.sharon@epa.gov'
Subject: RE: Clarentis LLC Registration - EPA Reg. No. 86854-1

Ms. Henson -

I am making an appeal on this issue by virtue of this email.

Request for a Change in Conditions of Registration

Clarentis LLC

Ultra-Lyte, EPA Reg. No. 86854-1

Background

The Ultra-Lyte product was issued a registration on November 17, 2010. This registration was issued with the following condition:

On page 3, add the statements "Ultra-Lyte must be produced on-site and must be used soon after being produced.."

The registered Ultra-Lyte product is substantially similar to other hypochlorous acid products registered by the Agency. One of those products has a 30-day limitation on distribution, the other has a 60-day limitation. The Clarentis product has a 30-day limitation, although we believe it to be more efficacious and is also more concentrated than the product with a 60-day limitation.

Neither of these substantially similar products require that the product be generated on-site. This requirement creates a very uneven playing field in that we cannot, according to the registration notice, distribute our product, but must generate it on-site, whereas, the substantially similar products just recently registered do not have that requirement. The very purpose for this registration is for Clarentis to be able to generate the registered material and distribute it to their customers. There are many customers (such as oil and gas companies) who cannot generate the material on-site. Without being able to distribute the registered product, Clarentis cannot provide for their customers.

The generator is already used on-site in certain instances as a pesticidal device and the only reason to obtain a registration is so that the generated solution can be distributed.

Requested Correction

We have language on the accepted label for the date of production and the 30-day limitation, as clearly shown on page one. Therefore, we would like condition number five eliminated from the Registration Notice and the Registration Notice reissued, withdrawing the previous notice from the PPLS system.

If you would rather; we have made all the other changes to the label which you required (as attached to this email). You could remove all of your conditions except for number 1 and stamp the new label, removing the previous notice from the PPLS system.

Either fix would solve this issue and Clarentis will be able to distribute the registered product.

Thank you for your consideration. We hope to resolve this issue quickly so that Clarentis can begin using their registration. Please contact me if you have any additional needs.

Bob Brennis - Agent for Clarentis LLC

Brennis Consulting Services LLC

6628 Birchleigh Way

Alexandria, VA 22315

Office: 703-922-6677

Cell: [redacted]

Personal privacy information

EPA_Label_for_Clarentis_1-4-11.pdf

Material to be added to an e-Jacket/Jacket

Reg. No. 86854-2

1. ☐ Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top/newest)
   - ☐ Description: (PDF page number, i.e., "before page 45")

   _____

   _____

2. ☒ Send to Data Extraction contractors this material:
   - ☒ Newly stamped accepted label
   - ☐ Notification
   - ☒ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Wanda Henson

Phone: _____ Division: AD

Date: 11/23/2010

Created January 26, 2009

TASK ASSIGNMENT FORM

Antimicrobi Division/Regulatory Manage ent Branches

Contractor: Arctic Slope Corporation	**Contract No:** EP-W-052 TO#122	**TOPO:** Kennetta Calloway / 703-305-0066 **Alternate:** Wanda Hall / 703-308-6383

A COMPLETED BY AD TEAM LEADER

Acting Team Leader / Phone Wanda Henson/308-6345	**AD Contact / Phone Number:** Wanda Henson 308-6345	**RMB I TEAM:**	**RMB II TEAM:** 32

Submission No.: 877665	**Decision No.:** 436827	**EPA File Symbol/Reg. No.:** 86854-R
PRIA Fee: $4,410	**EPA Action Code:** A540	**Estimated Govt. Hours:** 5

FQPA (Registration)	**Non-FQPA** ☐	**Product Re-registration** ☐

PRIA	**ME-TOO**	**New Use** ☐	**Old Chemical**	**New Chemical** ☐	**Amend w/data** ☐

	MONTH	DAY	YEAR
APPLICATION DATE	06	30	2010
EPA PIN DATE	07	01	2010
DATE PM RECEIVED FROM FRONT END	07	02	2010
DATE SENT TO SCIENCE			
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			
DATE DUE OUT OF AGENCY	11	27	2010
DUE DATE FROM CONTRACTOR	11	13	2010

PSB	**Product Chemistry** X	**Acute Toxicology** ☐	**Efficacy** X	
RASSB	**Environmental Fate** ☐	**Ecological Effects** ☐	**Chronic Toxicology** ☐	**Exposure/Residue** ☐
ATTACHMENTS	**LABELING** ☐	**CSF(S)**	**DATA** ☐	**OTHERS** ☐

AD Comments: Please provide hard and/or electronic copies of deliverable(s) as directed.

B COMPLETED BY AD TOPO

TAF Action Number: KC 1151 KRC 11/22/10

GPRA G/O/S: **TOPO Initials:** WH **Date Received:** 07-20-10 **Date Sent To ARSC:** 07-20-10

C COMPLETED BY ARSC TASK ORDER MANAGER (TOM)

Date Received:	TOM Initials:	Date Completed:	Response Code:	Response Date:	Hours to Complete:
7-20-10	D.A	11-17-10	1160	11/23/2010	17

ARSC Principal Reviewer: J Gray

ARSC Comments: Enclosed Product chemistry review is not signed.

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510C)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_x_ Registration
____ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
86854-1	11/17/2010

Term of Issuance: Conditional

Name of Pesticide Product: Ultra-Lyte

Name and Address of Registrant (include ZIP Code):

Clarentis, LLC
191 NE Boad Haven Road
Belfair, WA 98528

COPY

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product (OPP Decision No. 436827) is registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Change EPA File Symbol 86854-R to EPA Registration Number 86854-1.
3. On page 2, revise the Precautionary Statements by changing the statement "...chewing gum, or using tobacco." to read "...chewing gum, using tobacco or using the toilet."
4. On page 3, revise the statement "Anolyte is a colorless..." to read "The anolyte is a colorless..."
5. On page 3, add the statements "Ultra-Lyte must be produced on-site and must be used soon after being produced. The Ultra-Lyte product must be used within 30 days of production." following the statement "...dark area away from direct sunlight."
6. On page 3, add 'Pseudomonas aeruginosa' to the list of microorganisms beginning with an asterisk (*).

Signature of Approving Official:

Wanda Y. Henson
Acting Product Manager Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date: NOV 17 2010

EPA Form 8570-6

7. Any product that states or implies the use of a product as a general disinfectant on medical devices or medical equipment surfaces must have PR Notice 94-4 MOU language. On page 3, add the following statements to the "Hard, Non-Porous Surface Disinfection" section of the label:

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high-level disinfection.

8. On page 4, revise the claim "...Prevent(s) cross-contamination on hard, non-porous surfaces..." to read "...Prevent(s) cross-contamination between treated hard non-porous surfaces..." and "...cross-contamination on most hard, non-porous surfaces..." to read "...cross-contamination between treated hard non-porous surfaces...".

9. On page 7, change the statement "Food contact surfaces must be rinsed with clean, potable water" to read "Food contact surfaces must be rinsed with potable water after application of disinfectant".

10. On page 8:
    a. Delete the use sites 'Cooling Towers' and 'Lazy Rivers' as the product label doesn't include directions for use for these sites.
    b. Revise 'Pipelines' to read 'Pipelines associated with oil and gas production'.
    c. Delete the claim 'Non-food Produce Areas' as produce is food.

11. On page 10, delete the phrase "Similar hard, non-porous surfaces except those excluded by the label." as use sites must be specific and this statement is too broad.

12. On page 11, revise the statement "...979 US gallons of produced water to 10.5 ppm C..." to read "...979 US gallons of produced water to 10.5 ppm FAC..."

13. On page 11, revise the Storage and Disposal section as follows:
    a. Change the subheading 'Storage' to 'Pesticide Storage'
    b. Change "No refillable Container." to read "Nonrefillable Container."
    c. Add the statement "Triple rinse container (or equivalent) promptly after emptying." preceding the phrase "Triple rinse as follows..."
    d. Change "...rinse at a disposal." to read "...rinsate disposal."

14. Change 'Escherichia-ColiO 157:H7' to 'Escherichia-Coli O157:H7' wherever it appears on the label.

15. Remove all references to use site tables in relation to table numbers as there are no numbered tables included on the product label.

16. Add the heading 'Physical or Chemical Hazards' and place a statement regarding the incompatibility of the product with other chemicals (e.g. acids, hydrogen peroxide) as evidenced by the submitted data.

17. Submit the pending Storage Stability and Corrosion Characteristics studies to the Agency upon completion.

Submit one (1) copy of your final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Wanda Y. Henson
Acting Product Manager Team 32
Regulatory Management Branch II
Antimicrobials Division (7510P)

Ultra-Lyte™

Aqueous Solution of Sodium Chloride

Ultra-Lyte™ solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA
Ph: 866-363-7930 Email: info@ultra-lyte.com

EPA Reg. # 086854-R

EPA Est. # 086854-WA-001

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 17 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 86854-1

Ultra-Lyte™ must be used within 30 days after being produced. Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Ultra-Lyte™ is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte™** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte™** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte™** can be applied as a liquid or spray.

Ultra-Lyte™ freezes at 32° F and boils at 212° F. Anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte™** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-ColiO 157:H7, Listeria Monocytogenes.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Hard, Non-Porous Surface Disinfection

To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe, Spray or Dip]* **Ultra-Lyte™ at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects + Cleans and disinfects hard, non-porous surfaces
+ Cleans, deodorizes and disinfects

+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonell enterica, Pseudomonas aeruginosa, Escherichia-Coli O157, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)
+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination on hard, non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal + The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination on most hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces+ Us where control of the hazards of cross-contamination between treated surfaces is of Prime importance

GENERAL CLAIMS

+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding

and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.
Apply Ultra-Lyte™ (full strength) at 500 ppm FAC (Saturate surfaces with solution for 10 minutes. Immerse all
halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with clean, potable water)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with clean, potable water)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes

Blood Banks
Boats
Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Cooling Towers
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Lazy Rivers
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines
Preschool Facilities
Non-food Produce Areas
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes

CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens
Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum

Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks
Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.
Similar hard, non-porous surfaces except those excluded by the label

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte™ with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte™ into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of produced water to 10.5 ppm C, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte™ at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte™ into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a closed dark plastic container away from direct sunlight. Store container in a cool dry area

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: No refillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinse at a disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times, then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

November 17, 2010

DP BARCODE: 380286

MRID : 481398-01 thru 481398-03

SUBJECT: Ultra-Lyte
(Name of Product)

REG. NO.: 86854-R

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR End-use Product [x]

INGREDIENTS:

PC Code(s)	CAS Number	Active Ingredient(s):
129054	7790-92-3	Hypochlorous acid

TEST LAB: Case Consulting Laboratories, Inc.
ATS Labs

SUBMITTER: Clarentis, LLC

GUIDELINE: Product Chemistry Group A and B

ORGANIZATION: AD\PSB\CTT

REVIEWER: Earl Goad

APPROVED BY: Karen P. Hicks

APPROVED DATE: November 17, 2010

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

November 17, 2010

MEMORANDUM

SUBJECT: Product Chemistry Review for EPA Reg. 86854-R
Product Name: Ultra-Lyte
DP Barcode: 380286

CODE: (A540) New Product; Non-Fast Track; Fifra Section 2(MM) Uses

DATE DUE: November 27, 2010

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Wanda Henson (acting PM#32)/Sheri Gray
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Clarentis, LLC

PRODUCT FORMULATION FROM LABEL:

PC Codes	Active Ingredient(s):	% by wt.
129054	Hypochlorous acid	0.046
	Other Ingredient(s):	99.954
	Total:	100.00

BACKGROUND:

The registrant has submitted an application for registration of a new end-use product, Ultra-Lyte. The product is for use as a disinfectant (bactericide, virucide) and deodorizer on hard, non-porous surfaces in institutional, industrial, food service, animal care, and hospital or medical environments.

The active ingredient is produced from a brine solution using an electrolytic cell. The properties of the resulting solution can be precisely controlled by adjusting power to the cell, flow rate and conductivity of the brine in the cell.

The concentration of hypochlorous acid is based on the pH related equilibrium between hypochlorite and hypochlorous forms and therefore is subject to the pH and available concentration of available chlorine.

The product is produced by an integrated formulation system (i.e., the product contains an active ingredient that is not sourced from an EPA-registered product)

The data package included:

1. a letter from the applicant's representative to EPA, dated June 30, 2010;
2. EPA Form 8570-1 (Application for Pesticide), dated June 22, 2010; a
3. Confidential Statement of Formula (CSF) for the basic formulation, dated June 22, 2010 (pre-reaction and post-reaction);
4. EPA Form 8570-34 (Certification with Respect to Citation of Data), dated June 30, 2010;
5. EPA Form 8570-35 (Data Matrix), dated June 22, 2010;
6. A proposed product label;
7. An MSDS sheet for the product.
8. Three product chemistry studies
    a. Product Chemistry Group A MRID No. 481398-01
    b. Product Chemistry Group B MRID No. 481398-02
    c. Preliminary Analysis: MRID No. 481398-03
9. Revised/corrected CSF dated 10/4/2010.

FINDINGS:

1. Confidential Statement of Formulation:
   Revisions to the CSF (post-reaction stage) must be made. The registrant was informed and a signed revised CSF dated 10/4/2010 was received and found to be acceptable.

2. Product Label: The following revisions to the product label must be made:
    a. Add the heading "Physical or Chemical Hazards" to the product label.
    b. Under the new "Physical or Chemical Hazards" section of the product label, place a statement regarding the incompatibility of the product with other chemicals (e.g., acids, hydrogen peroxide) as evidenced by the data provided in response to OPPTS 830.6314 (Oxidation/ Reduction; Chemical Incompatibility) requirements and information contained on the MSDS.
    c. Under the "Storage and Disposal" section of the product label, change the "Storage" subheading to read "Pesticide Storage."

d. Under the "Pesticide Disposal" section of the product label, provide instructions for disposing of unused product. Guidance on developing appropriate pesticide disposal instructions can be found at http://www.epa.gov/oppfead1/labeling/lrm/, Chapter 13 (Storage and Disposal).
e. It is recommended to revise the product label to include under the "Pesticide Storage" section of the product label, instructions that specify what to do if the product leaks or spills from the product container.
f. Label Page 2 of 9 middle of 9th line down, the sentence beginning with "Anolyte is a colorless ..." Please re-phrase to read "The anolyte is a colorless .... ("Anolyte" is the product name of a similar previously registered product.- while anolyte is the generic term intended to refer to the solution on the anode side of the electrolytic cell)
g. The label must contain a place to record production date and the date the product was opened and put into use. Once the product is opened and has been put into use the stability of the solution is compromised. The registrant must provide some stability data to support a recommended useful life upon opening. Alternatively, label as dispose of material if the ppm available chloride drops below a set amount such as 450 ppm.

3. Product Chemistry: The detailed list of the product chemistry is found in Table A and B below.
    a. Product Chemistry Group A data requirements have been addressed.
    b. Product Chemistry Group B data requirements are still incomplete with respect to storage stability and corrosion characteristics of the product. This study is reported as being in process to be reported as being underway. The results of this study must be submitted for review upon completion.
        i. Expiration of the unopened product is required to be based upon the storage stability study. The elapsed time within which the concentration of active ingredient remains within the certified limits.
        ii. Additional concern exists for how long this product might last once the container has been opened and placed into use. It is a different set of circumstances than that provided by the long term stability study. The effectiveness of the product would be expected to change with significant pH changes or loss of available chlorine from the solution.

CONCLUSION:

The revised CSF dated 10/4/2010 is found to be acceptable. There are numerous issues regarding the proposed product label. The product chemistry data requirements have been satisfied with the exception of the storage stability and corrosion characteristics.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system — Yes [ ] No [X]
- Are all TGAIs used registered? — Yes [ ] No [x]
- Integrated formulation system — Yes [X] No [x]
- If "ME-TOO," specify EPA Reg. No. of existing product: 82341-1

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [x]
Note: *Food contact use according to* 40 CFR §180.940 states the tolerance exemption for Hypochlorous acid as not to exceed 200 ppm. This product contains 460 ppm hypochlorous acid

Note: All formulation components are listed on the EPA document "Inert Ingredients Permitted for Use in Nonfood Use Pesticide Products," last updated on March 28, 2010 and available at http://www.epa.gov/opprd001/inerts/inert_nonfooduse.pdf.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [X] No [ ]

e. The NCs and CLs are acceptable. Yes [X] No [ ]

Note: Standard certified limits were proposed for the diluent and impurity.

Note: A non-standard certified upper limit was proposed for the active ingredient. An explanation of the basis for the non-standard limit was provided. The explanation appears sound.

f. Active ingredient	NC (%)	LCL (%)	UCL (%)
Hypochlorous acid [as identified on the product label] †Calculated	0.046	0.041	0.055

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [X] No [ ] Not applicable [ ]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [x] No [ ]

Note: The nominal concentrations, upper certified limits, and lower certified limits appear to be incorrectly reported on the CSF. This error was corrected on a subsequent revised CSF dated 10/4/2010.

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [ ] No [ ]

Note: Disposal options for unused pesticide must be identified. See the label section of findings.

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A Note: Nominal concentrations, upper certified limits, and lower certified limits as originally reported appear to be incorrect. This was corrected in a subsequent revised CSF dated October 4, 2010..	481398-01 and CSF
830.1600 Description of Materials	A	481398-01 and CSF
830.1620 Production Process[2]	A	481398-01
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	481398-01
830.1700 Preliminary Analysis[5]	A – Results from the analysis of five batches of the product were provided. Testing was conducted in compliance with GLP.	481398-03
830.1750 Certified Limits[6]	A – Standard certified limits were proposed for the diluent and impurity. A non-standard certified upper limit was proposed for the active ingredient. An explanation of the basis for the non-standard limit was provided. The explanation appears sound. G – A signed certification statement must be provided, as requested under OPPTS 830.1750(g).	481398-01
830.1800 Analytical Method[7]	A – A copy of a colorimetric sodium thiosulfate titration method was provided.	481398-01 and 481398-03
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The product is colorless at 20°C, based on a visual inspection. CCL SOP 10.11 was referenced. Testing was conducted in compliance with GLP.	481398-02
830.6303 Physical State	A	The product is a liquid at 20°C, based on a visual inspection. CCL SOP 10.12 was referenced. Testing was conducted in compliance with GLP.	481398-02
830.6304 Odor	A	The product has a chlorine-like odor at 20°C. CCL SOP 10.13 was referenced. Testing was conducted in compliance with GLP.	481398-02
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	The product contains hypochlorous acid, which is a known oxidizer. Note: The MSDS for the product indicates to avoid accidental or uncontrolled contact of the product with acids and hydrogen peroxide.	481398-02
830.6315 Flammability/ Flame Extension	A	The product consists of 99.5% water.	481398-02
830.6316 Explodability	A	The product components show no potential for explosive properties.	481398-02
830.6317 Storage Stability	G	A storage stability study is currently underway. Results will be provided to EPA once the study is complete.	Letter to EPA, dated 6/30/2010
830.6319 Miscibility[1]	A	The product is ready-to-use.	Label
830.6320 Corrosion Characteristics	G	To be included with storage stability 830.6317	
830.6321 Dielectric Breakdown Voltage	NA	Product is not labeled for use near electrical equipment	
830.7000 pH[2]	A	The pH of the product was reported to be 5.37 at 25°C. A 1% (w/w) mixture of the product in deionized water was tested. CCL SOP 10.17, which is based on ASTM E 70, was referenced. Testing was conducted in	481398-02

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		compliance with GLP. Note: A pH range of 6.35-6.40 was reported for 5 preliminary analysis samples.	
830.7050 UV/Visible Absorption	NA	*[Not required for end-use products.]*	
830.7100 Viscosity	A	The mean kinematic viscosity of the product was reported to be 0.9844 mm^2/s (cSt) at 21°C and 0.6346 mm^2/s (cSt) at 41°C (as determined using an Ubbelohde viscometer). Two determinations were made at each temperature. ASTM D 445 and D 446 were referenced. Testing was conducted in compliance with GLP.	481398-02
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The relative density of the product was reported to be 1.0088 at 20°C. CCL SOP 10.16, which is based on ASTM D 891, Method B, was referenced. Testing was conducted in compliance with GLP.	481398-02
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 18, 2010

MEMORANDUM

Subject: Efficacy Review for Ultra-Lyte; EPA File Symbol 86854-R; DP Barcode: D380287.

From: Ibrahim Laniyan, Microbiologist
Product Science Branch
Antimicrobials Division (7510P)

Thru: Tajah Blackburn, Team Leader
Product Science Branch
Antimicrobials Division (7510P)

10/27/10

To: Sherri Gray / Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Clarentis LLC
191 NE Boad Haven Road
Belfair, WA 98528

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hypochlorous Acid	0.046 %
Other Ingredients	99.954 %
Total	100.000 %

(Contains 500 ppm Free Available Chlorine (FAC))

I. BACKGROUND

The product, Ultra-Lyte (EPA File Symbol 86854-R), is a new product, **generated using a specific instrument only when intended to be used soon after being produced** (no more then 30 days). The applicant requested to register the product as a cleaner/disinfectant (bactericide and virucide) for use on hard, non-porous surfaces in household environments, industrial areas commercial, food processing, animal care, and hospital or medical environments. The label claims that the product is a "one-step" disinfectant (i.e., effective in the presence of an organic soil load). The applicant claims that this product is substantially similar to EcaFlo® Anolyte (EPA Reg. No. 82341-1). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D380287 contained a letter from the applicant representative to EPA (dated June 30, 2010), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-4 (Confidential Statement of Formula), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), six studies (MRID Nos. 481398-04 through 481398-09), Statement of No Data Confidentiality Claims for all six studies, and the proposed label (e-mailed on October 18, 2010).

II. USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as door handles, clean-up carts, light switches, sinks, tubs, tiles, toilets, shower doors, floors, dressing or linen carts, hampers, diaper pails, toilet seats, bed pans, plastic mattress covers, lockers... Directions on the proposed label provided the following information regarding use of the product as a disinfectant: Apply Ultra-Lyte at **500ppm** FAC to hard, non-porous surface to be disinfected. Use sufficient Ultra-Lyte for treated surface to remain visibly wet for contact time listed on label. Let air dry. Any surface that may come in contact with food should be washed with clean, potable water. Gross filth must be removed prior to disinfecting.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria): The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). To support products labeled as "general disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Disinfectants for Use on Hard Surfaces (Against a Broad Spectrum of Bacteria; Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against specific bacteria with each of 2 product samples, representing 2 different product lots. To support products labeled as

"disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific bacteria on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Supplemental Claims: An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV. COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 481398-04: "AOAC Use Dilution Method Using *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella enterica* (ATCC 10708)." for Ultra-Lyte, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 22, 2010. Project ID Number A09168.

This study was conducted against *Staphylococcus aureus* (ATCC 6538), *Pseudomonas aeruginosa* (ATCC 15442), and *Salmonella enterica* (ATCC 10708). Three lots (UL-01, UL-02, and UL-03) of the product, Ultra-Lyte, were tested, according to ATS Labs protocol # CLS01012010.UD.2 (copy provided), against the target microorganisms for a contact time of 10 minutes at ambient room temperature (20.0°C). The test substance lots were produced at ATS Labs as a ready to use product. Fetal bovine serum was added to the inoculum at a concentration of 5% to simulate an organic soil load; Letheen Broth with 0.2% Sodium Thiosulfate, was used as neutralizing subculture medium; and Tryptic Soy with 5% Sheep Blood Agar (BAP) was used as agar plate medium. Stainless steel penicylinders (carriers) were contaminated (15 minutes at ambient temperature) at a ratio of one carrier per 1.0ml of 48-54 hours cultured inoculum broth and dried at 35-37°C for 40 minutes at 41% relative humidity. Sixty carriers were tested per batch per microorganism. Following exposure, the carriers were transferred to the neutralizing medium, incubated for 46 hours at 35-37°C, stored for 1 day at 2-8°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. The reported average

colony forming units per carrier, for the tested microorganisms are: ***Staphylococcus aureus*** **1.7 x 10^7**, ***Pseudomonas aeruginosa*** **1.58 x 10^6, and *Salmonella enterica* 1.27 x 10^6.**

2. MRID 481398-05: "AOAC Use Dilution Method Using *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708)." for Ultra-Lyte, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 24, 2010. Project ID Number A09449.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708). One over 60 days old lot (UL-01) of the product, Ultra-Lyte, was tested, according to ATS Labs protocol # CLS01041910.UD.1 (copy provided), against the target microorganism for a contact time of 10 minutes at ambient room temperature (20.0°C). The test substance lot was produced at ATS Labs as a ready to use product at the ATS Labs in a white, HDPE bottle at room temperature which was filled to the top on the day of manufacture to eliminate air/head space in the bottle. Fetal bovine serum was added to the inoculum at a concentration of 5% to simulate an organic soil load; Letheen Broth with 0.2% Sodium Thiosulfate, was used as neutralizing subculture medium; and Tryptic Soy with 5% Sheep Blood Agar (BAP) was used as agar plate medium. Stainless steel penicylinders (carriers) were contaminated (15 minutes at ambient temperature) at a ratio of one carrier per 1.0ml of 48-54 hours cultured inoculum broth and dried at 35-37°C for 40 minutes at 39% relative humidity. Sixty carriers were tested per microorganism. Following exposure, the carriers were transferred to the neutralizing medium, incubated for 48±4 hours at 35-37°C then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. The reported average colony forming units per carrier, for the tested microorganisms are: ***Staphylococcus aureus*** **8.6 x 10^6 and *Salmonella enterica* 5.0 x 10^6.**

3. MRID 481398-06: "AOAC Use Dilution Method Using *Escherichia coli O157:H7* (ATCC 35150)." for Ultra-Lyte, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 19, 2010. Project ID Number A09173.

This study was conducted against *Escherichia coli O157:H7* (ATCC 35150). Two product lots (UL-06 and UL-7) of the product, Ultra-Lyte, were tested, according to ATS Labs protocol # RUV01021910.UD.1 (copy provided), against the target microorganism for a contact time of 10 minutes at ambient room temperature (20.0°C). The test substance lots were produced at ATS Labs as a ready to use product. Fetal bovine serum was added to the inoculum at a concentration of 5% to simulate an organic soil load; Letheen Broth with 0.2% Sodium Thiosulfate, was used as neutralizing subculture medium; and Tryptic Soy with 5% Sheep Blood Agar (BAP) was used as agar plate medium. Stainless steel penicylinders (carriers) were contaminated (15 minutes at ambient temperature) at a ratio of one carrier per 1.0ml of 48-54 hours cultured inoculum broth and dried at 35-37°C for 40 minutes at 42% relative humidity. Ten carriers were tested per product lot. Following exposure, the carriers were transferred to the neutralizing medium, incubated for 45 hours at 35-37°C, stored for 1 day at 2-8°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. The reported average colony forming units per carrier, for the tested microorganisms are: ***Escherichia coli O157:H7*** **7.4 x 10^5.**

4. MRID 481398-07: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A (H1N1) virus" for Ultra-Lyte, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – March 29, 2010. Project Number A09150.

This study was conducted against Influenza A (H1N1) virus (Strain A/PR/8/34; ATCC VR-1469), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (UL-01 and UL-2) of the product, Ultra-Lyte, were tested according to ATS Labs Protocol No. CLS01020810.FLUA (copy provided). The test substance lots were produced at ATS Labs as a ready to use product. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 40% relative humidity. For each lot of product, separate dried virus films were individually exposed to 2.00 ml aliquot of test substance and held covered for 10 minutes at 20.0°C. Following exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed immediately through individual Sephadex columns, and diluted serially in Minimum Essential Medium with 1% heat-inactivated fetal bovine serum, 10 µg/mL gentamicin, 100 units/mL penicillin, and 2.5 µg/mL amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 mL of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for input virus count, dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

5. MRID 481398-08: "AOAC Use Dilution Method Using *Listeria monocytogenes* (ATCC 19111)." for Ultra-Lyte, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 18, 2010. Project ID Number A09174.

This study was conducted against *Listeria monocytogenes* (ATCC 19111). Two product lots (UL-06 and UL-7) of the product, Ultra-Lyte (Halosol), were tested, according to ATS Labs protocol # RUV01021910.UD.2 (copy provided), against the target microorganism for a contact time of 10 minutes at ambient room temperature (20.0°C). The test substance lot was produced at ATS Labs as a ready to use product. Fetal bovine serum was added to the inocula at a concentration of 5% to simulate an organic soil load; Letheen Broth with 0.2% Sodium Thiosulfate, was used as primary neutralizing subculture medium; Brain Heart Infusion Broth as secondary; and Tryptic Soy with 5% Sheep Blood Agar (BAP) was used as agar plate medium. Stainless steel penicylinders (carriers) were contaminated (15 minutes at ambient temperature) at a ratio of one carrier per 1.0ml of 48-54 hours cultured inoculum broth and dried at 35-37°C for 40 minutes at 44% relative humidity. Ten carriers were tested per product lot. Following exposure, the carriers were transferred to the primary neutralizing medium, then into secondary subculture medium after 30 minutes; incubated for 45 hours at 35-37°C, stored for 1 day at 2-8°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. The reported average colony forming units per carrier, for the tested microorganisms are: ***Listeria monocytogenes* 4.5×10^6.**

6. MRID 481398-09: "AOAC Use Dilution Method Using Methicillin Resistant *Staphylococcus aureus* - MRSA" for Ultra-Lyte, by Joshua Luedtke. Study conducted at ATS Labs. Study completion date – March 22, 2010. Project ID Number A09167.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33591). Two lots (UL-01 and UL-2) of the product, Ultra-Lyte, were tested, according to ATS Labs protocol # CLS01012510.UD (copy provided), against the target microorganism for a contact time of 10 minutes at ambient room temperature (20.0°C). The test substance lots were produced at ATS Labs as a ready to use product. The stock virus culture contained 5% fetal bovine serum as the organic soil load. The test substance lots were produced at ATS Labs as a ready to use product. Fetal bovine serum was added to the inoculum at a concentration of 5% to simulate an organic soil load; Letheen Broth with 0.2% Sodium Thiosulfate, was used as neutralizing subculture medium; and Tryptic Soy with 5% Sheep Blood Agar (BAP) was used as agar plate medium. Stainless steel penicylinders (carriers) were contaminated (15 minutes at ambient temperature) at a ratio of one carrier per 1.0ml of 48-54 hours cultured inoculum broth and dried at 35-37°C for 40 minutes at 42% relative humidity. Ten carriers were tested per product lot. Following exposure, the carriers were transferred to the neutralizing medium, incubated for 45 hours at 35-37°C, stored for 1 day at 2-8°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population. For the dried colony counts, carrier/neutralizing broth mixtures were vortex mixed. The reported average colony forming units per carrier, for the tested microorganisms are: **Methicillin Resistant *Staphylococcus aureus* - MRSA 6.6 x 10^6.**

V. RESULTS

MRID #	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population Count (CFU/carrier)
		UL-01	UL-02	UL-03	
481398-04	*Staphylococcus aureus*	0/60	0/60	0/60	1.47 x 10^7
	Salmonella enterica	0/60	0/60	0/60	1.27 x 10^6
	Pseudomonas aeruginosa	0/60	1/60	1/60	1.58 x 10^6
481398-05	*Staphylococcus aureus*	1/60	-	-	8.6 x 10^6
	Salmonella enterica	0/60	-	-	5.0 x 10^6
481398-09	Methicillin Resistant *Staphylococcus aureus*	0/10	0/10	-	6.6 x 10^6
		UL-06	**UL-07**		
481398-06	*Escherichia coli O157:H7*	0/10	0/10	-	7.4 x 10^5
481398-08	*Listeria monocytogenes*	1°= 0/10 2°= 0/10	1°= 0/10 2°= 0/10	-	4.5 x 10^6

MRID Number	Organism	Results			Dried Virus Count
			UL-01	UL-02	
481398-07	Influenza A (H1N1) virus	10^{-1} to 10^{-7} dilution	Complete inactivation	Complete inactivation	$10^{6.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
		Log reduction	≥ 6.25 $\log_{10}$	≥ 6.25 $\log_{10}$	

VI. CONCLUSIONS

1. Product lots used in efficacy studies were not analyzed at the time of production/testing to make sure that they are tested at the lower end of the acceptable range. The Agency lacks critical information on the lot kept for 60 days before testing. **Claims for 60 days old product cannot be made**.

2. The submitted efficacy data **support** the use of the product, Ultra-Lyte, as a disinfectant with bactericidal activity against the following microorganism, when used undiluted, on hard, non-porous surfaces at ambient temperature in the presence of a 5% organic soil load for a contact time of 10 minutes.

Staphylococcus aureus (ATCC 6538)	MRID 481398-04
Pseudomonas aeruginosa (ATCC 15442)	MRID 481398-04
Salmonella enterica (ATCC 10708)	MRID 481398-04
Escherichia coli O157:H7 (ATCC 35150)	MRID 481398-06
Listeria monocytogenes (ATCC 19111)	MRID 481398-08
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33591)	MRID 481398-09

3. The submitted efficacy data (MRID 481398-04) **support** the use of the product, Ultra-Lyte, as a disinfectant with virucidal activity against Influenza A (H1N1) virus, when used undiluted, on hard, non-porous surfaces in the presence of at least a 5% organic soil load for a 10-minute contact time.

VII. Label

1. This product, like the "me-too" product (EcaFlo® Anolyte) must be generated on-site for immediate use only. **Any attempt to generate the product at a site different than the use site is unacceptable**. **The use of this product at a site different than the production site must be supported by data generated in those conditions**.

2. The proposed label claims that the product, Ultra-Lyte, is an effective one-step disinfectant against the following microorganisms, **when produced on-site** and used on-site undiluted **just after production**, or used on-site **within 30 days after production days when properly stored**, for a contact time of 10 minutes at room temperature:

Staphylococcus aureus (ATCC 6538)
Pseudomonas aeruginosa (ATCC 15442)

Salmonella enterica (ATCC 10708)
Escherichia coli O157:H7 (ATCC 35150)
Listeria monocytogenes (ATCC 19111)
Methicillin Resistant *Staphylococcus aureus* - MRSA (ATCC 33591)
Influenza A (H1N1) virus

These claims **are acceptable** as they are supported by the submitted data. **This product must not be shipped**.

3. The applicant must make the following changes to improve the proposed label:

- On page 3 of the proposed label, add ***Pseudomonas aeruginosa*** to the list of microorganisms under the start (*) before Disinfectant Applications.

- On pages 3 and 4 of the proposed label, change "**Escherichia-ColiO 157:H7**" to read "***Escherichia coli O157:H7***".

- On page 4 of the proposed label, remove all the " **... from table 1, 1-5, 5, or above**".

Brennis Consulting Services LLC

6628 Birchleigh Way, Alexandria, VA 22315
703-922-6677
Brennis.bob@gmail.com

June 30, 2010

U.S. Environmental Protection Agency
Document Processing Desk (7504P)
Room S-4900
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

ATTENTION: **Wanda Henson**
Product Manager, Team 32

SUBJECT: ***Clarentis LLC***
Ultra-Lyte ^{TM} ***(EPA Appl.No. 86854-R)***
Me Too Registration

Dear Ms. Henson:

On behalf of Clarentis LLC, I am submitting an application for the registration of a "me too" product, ***Ultra-Lyte*** ^{TM}. This product is substantially similar to EcaFlo Anolyte.

Data Requirements

The generic data is satisfied by citing available sodium hypochlorite data. We have generated our own product chemistry data and efficacy data for submission. The product specific acute toxicity data is supported by using the selective "cite all" method of support. This product qualifies as a A532 submission with a four month review time. This requires a payment of $4,200 and is being paid electronically.

Storage Stability

As indicated in the submitted efficacy testing, an aged sample (60 days old) was used for testing and the data is acceptable. Clarentis LLC is in the process of running stability studies for Ultra-Lyte that will show the product to be stable for one year. We will submit these studies to the Agency as they become available, but request that we be granted full registration and have the Agency make the stability studies a condition of registration as is normal.

This application includes the following documents:

1. One copy of the Application Form (8570-1)
2. One copy of letter of authorization
3. One copy of the Certification with Respect to Data (8570-34)
4. Two copies of the Confidential Statement of Formula (8570-4) (pre-reaction)
5. Two copies of the Confidential Statement of Formula (8570-4) (post-reaction)
6. One copy of the data matrix (8570-35)
7. Five copies of the proposed label
8. Two copies of the transmittal document identifying the submitted data (9 Volumes).
9. Three copies of each of the nine identified studies

If you have any questions about the enclosed submission, please contact me by telephone at 703-922-6677 or by e-mail at Brennis.bob@gmail.com .

Sincerely,

Robert S. Brennis
Agent for,
Clarentis LLC.

CLARENTIS LLC

March 2, 2010

Ms. Joan Harrigan-Farrelly
Director, Antimicrobial Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive (South Building)
Arlington, VA 22202

Dear Ms. Harrigan-Farrelly:

This letter authorizes Mr. Bob Brennis of Brennis Consultants Services LLC, of 6628 Birchleigh Way, Alexandria, VA 22315, to act as agent on behalf of Clarentis LLC on all matters that may come before the U.S. Environmental Protection Agency.

Sincerely,

Duke van Kalken
Clarentis LLC

191 NE Boad Haven Road, Belfair, WA 98528, Tel: (866)-363-7930
E-mail: [redacted]

Personal privacy information

Brennis Consulting Services LLC

6628 Birchleigh Way, Alexandria, VA 22315
703-922-6677
Brennis.bob@gmail.com

June 30, 2010

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Sincerely,

Robert S. Brennis
Agent for,
Clarentis LLC.

EPA TRANSMITTAL DOCUMENT
CLARENTIS LLC- ULTRA-LYTE

SUBMISSION DATED:	**June 30, 2010**
STUDY SUBMITTER:	**Clarentis LLC**
SUBMITTED IN SUPPORT OF:	**Ultra-Lyte**
EPA REGISTRATION NO.:	**86854-R**
REGULATORY ACTION:	**Application for Pesticide Registration – Old Chemical**
STUDIES SUBMITTED:	**8 Volumes**
STUDY VOLUME 1 of 9:	Chemistry Data for Ultra-Lyte (June 22, 2010) by Robert S. Brennis; 10 pages non-confidential, 12 pages confidential appendix. *US EPA Guidelines 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800* MRID Number: **48139801**
STUDY VOLUME 2 of 9:	Physical and Chemical Characteristics for Ultra-Lyte (June 10, 2010) by David J.Sinning; 7 pages. *US EPA Guidelines 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.7000.830.7100 & 830.7300* MRID Number: **48139802**
STUDY VOLUME 3 of 9:	Determination of Available Chlorine, pH and Hypochlorous Acid Concentration for Ultra-Lyte (April 29, 2010) by Amy S. Jeske,,ATS Labs; 23 pages. US EPA Guidelines 885.1400 MRID Number: **48139803**
STUDY VOLUME 4 of 9:	Efficacy Testing – Pseudomonas aeruginosa (ATCC 15442) Staphylococcus aureus (ATCC 6538) and Salmonella enterica (ATCC 10708) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 24 pages. MRID Number: **48139804**

STUDY VOLUME 5 of 9: Efficacy Testing – Staphylococcus aureus (ATCC 6538) and Salmonella enteric (ATCC 10708) 60 day aged test for Ultra-Lyte (May 24, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139805**

STUDY VOLUME 6 of 9: Efficacy Testing – Escherichia coli 0157:H7 (ATCC 35150) for Ultra-Lyte (March 19, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139806**

STUDY VOLUME 7 of 9: Efficacy Testing – Influenza A (H1N1) virus (ATCC VR 99) for Ultra-Lyte (March 29, 2010) by Kelleen Gutzmann,M.S., ATS Labs: 24 pages.

MRID Number: **48139807**

STUDY VOLUME 8 of 9: Efficacy Testing – Listeria monocytogenes (ATCC 19111) for Ultra-Lyte (March 18, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139808**

STUDY VOLUME 9 of 9: Efficacy Testing – Methicillin Resistant Staphylococcus Aureus – MRSA (ATCC 33592) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139809**

Company Contact:

Robert S. Brennis
Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
703-922-6677
brennis.bob@gmail.com

Please read instructions on reverse before c leting form. Form Appr OMB No. 2070-0060

EPA ited States **Environmental Protection Agency** Washington, DC 20460

☒ Registration ☐ Amendment ☐ Other

OPP Identifier Number XXXXXX

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
86854-R	Wanda Henson	☒ None ☐ Restricted
4. Company/Product (Name) **Clarentis LLC/ Ultra-Lyte ™**	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* **Clarentis LLC** 191 NE Boad Haven Road Belfair, WA ***PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW*** ☒ *Check if this is a new address*	6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 82341-1 Product Name EcaFlo Anolyte	

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☒ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This product is substantially similar to EcaFlo Anolyte. The generic data is satisfied by citing available sodium hypochlorite data. The product specific data is satisfied by conducting our own chemistry data and efficacy data and using "cite all" method of support for acute toxicity data. This product qualifies as a A532 submission with a four month review time. Please contact me at 703-922-6677 or at my email address, Brennis.bob@email.com if you need to contact me for any additional information.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1 pint, 1 quart, ½ gallon	☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No. (Include Area Code)
Robert S. Brennis, Brennis Consulting Services, 6628 Birchleigh Way, Alexandria, VA 22315	Agent	703-922-6677

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
R S Brennis	**Agent**	**(Stamped)**
4. Typed Name: Robert S. Brennis	5. Date: *June 22, 2010*	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete — White- EPA File Copy (original) — Yellow- Applicant Copy

Ultra-Lyte™

Aqueous Solution of Sodium Chloride

Ultra-Lyte™ solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in medical, institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA
Ph: 866-363-7930 Email: info@ultra-lyte.com

EPA Reg. # 086854-R

EPA Est. # 086854-WA-001

Ultra-Lyte™ must be used within 30 days after being produced. Store in a cool area and do not break the seal on the bottle until ready for use.

Date produced:

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals
CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

Ultra-Lyte™ is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte™** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte™** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte™** can be applied as a liquid or spray.

Ultra-Lyte™ freezes at 32° F and boils at 212° F. Anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte™** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight.

*Salmonella Enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-ColiO 157:H7, Listeria Monocytogenes.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Hard, Non-Porous Surface Disinfection

To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe,Spray or Dip]* **Ultra-Lyte™ at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10 minutes
Staphylococcus aureus MRSA ATCC 33591	10 minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes
Pseudomonas aeruginosa	10 minutes

Claims:

+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects + Cleans and disinfects hard, non-porous surfaces
+ Cleans, deodorizes and disinfects

+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa, Escherichia-Coli O157, Listeria Monocytogenes
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Escherichia-Coli O157
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Listeria Monocytogenes
+ Fight(s)– and/or – Kill(s) – and/or – Effective against Swine Influenza virus (H1N1)
+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination on hard, non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Ready–to–use hospital disinfectant
+ Staphylocidal + The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination on most hard, non-porous surfaces
+ This product meets AOAC efficacy testing requirements – or standards for hospital disinfection
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces+ Us where control of the hazards of cross-contamination between treated surfaces is of Prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ Suitable for hospital use
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Medical Uses

USE SITES:
Ambulances – or– Emergency Medical Transport Vehicles
Anesthesia Rooms – or Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central – Supply Rooms – or – Areas
Critical Care Units – or – CCUs
Dialysis Clinics
Emergency Rooms – or – ERs
Health Care Settings – or Facilities
Home Health Care Settings
Hospitals
Hospital Kitchens
Intensive Care Units – or ICUs
Laboratories
Medical Clinics
Medical Facilities
Medical – or – Physician's – or Doctor's Offices
Newborn – or – Neonatal Nurseries
Nursing – or – Nurses' Stations
Orthopedics
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Physical Therapy Rooms – or – Areas
Radiology – or – X-Ray Rooms – or – Areas
Surgery Rooms – or –Operating rooms – or – Ors

SURFACES
Bedpans
Exam – or – examination tables
External surfaces of medical equipment – or – medical equipment surfaces
External surfaces of ultrasound transducers
Gurneys
Hard, non-porous environmental hospital – or medical surfaces
Hospital – or – patient bed railings – or – linings – or – frames
IV poles
Patient chairs
Plastic mattress covers
Reception counters – or – desks – or – areas
Stretchers
Wash basins
Wheelchairs

Dental Uses

USE SITES:
Dental Operatories
Dentist – or – Dentist's offices

SURFACES:
Dental countertops
Dental operatory surfaces
Dentist – or – dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or – desks – or – areas

Veterinary Uses

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding

and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.
Apply Ultra-Lyte™ (full strength) at 500 ppm FAC (Saturate surfaces with solution for 10 minutes. Immerse all
halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

Food Service

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with clean, potable water)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with clean, potable water)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses

USE SITES
Airplanes

Blood Banks
Boats
Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Cooling Towers
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories
Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Lazy Rivers
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines
Preschool Facilities
Non-food Produce Areas
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes

CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens
Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas
Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum

Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks
Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers
Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.
Similar hard, non-porous surfaces except those excluded by the label

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte™ with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte™ into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of produced water to 10.5 ppm C, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte™ at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte™ into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a closed dark plastic container away from direct sunlight. Store container in a cool dry area

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: No refillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinse at a disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times, then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

Decision #: 436827

DATA PACKAGE BEAN SHEET

DP #: (380286)

Date: 20-Jul-2010

PRIA

Parent DP #:

Submission #: 877665

* * * Registration Information * * *

Registration: 86854-R - ULTRA-LYTE

Company: 86854 - CLARENTIS, LLC

COPY FOR YOUR INFORMATION

Risk Manager: RM 32 - Wanda Henson - (703) 308-6345 Room# PY1 S-8232

Risk Manager Reviewer: Sherri Gray SGRAY02

Sent Date: _____ Calculated Due Date: 27-Nov-2010 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 129054, Hypochlorous Acid(.046%)

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 20-Jul-2010 Due Back: _____

DP Ingredient: 129054, Hypochlorous Acid

DP Title: _____

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out		
Organization:	AD / PSB			Last Possible Science Due Date:	28-Oct-2010
Team Name:	CTT			Science Due Date:	
Reviewer Name:				Sub Data Package Due Date:	
Contractor Name:					

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

product chemistry: Please review the attached cover letter, label, CSFs (post & pre reaction stage), MSDS, data matrix and studies 481398-01, -02 & -03 submitted to support registration of subject's product.

Decision #: 436827

DATA PACKAGE BEAN SHEET

DP #: (380287)

Date: 20-Jul-2010

PRIA

Parent DP #:

Submission #: 877665

* * * Registration Information * * *

Registration: 86854-R - ULTRA-LYTE

COPY FOR YOUR INFORMATION

Company: 86854 - CLARENTIS, LLC

Risk Manager: RM 32 - Wanda Henson - (703) 308-6345 Room# PY1 S-8232

Risk Manager Reviewer: Sherri Gray SGRAY02

Sent Date: Calculated Due Date: 27-Nov-2010 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (A540) NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

Ingredients: 129054, Hypochlorous Acid(.046%)

* * * Data Package Information * * *

Expedite: ◯ Yes ● No Date Sent: 20-Jul-2010 Due Back:

DP Ingredient: 129054, Hypochlorous Acid

DP Title:

CSF Included: ● Yes ◯ No Label Included: ● Yes ◯ No Parent DP #:

Assigned To	Date In	Date Out
Organization: AD / PSB		
Team Name: EET		
Reviewer Name:		
Contractor Name:		

Last Possible Science Due Date: 28-Oct-2010

Science Due Date:

Sub Data Package Due Date:

* * * Studies Sent for Review * * *

Printed on Page 2

* * * Additional Data Package for this Decision * * *

Can be printed on its own page

* * * Data Package Instructions * * *

Efficacy: Please review the attached cover letter, label, CSFs, data matrix & studies MRID#s 481398-04 thru -09 submitted to support registration of subject's product.

Brennis Consulting Services LLC

6628 Birchleigh Way, Alexandria, VA 22315
703-922-6677
Brennis.bob@gmail.com

June 30, 2010

U.S. Environmental Protection Agency
Document Processing Desk (7504P)
Room S-4900
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

ATTENTION: **Wanda Henson**
Product Manager, Team 32

SUBJECT: ***Clarentis LLC***
Ultra-Lyte ™ (EPA Appl.No. 86854-R)
Me Too Registration

Dear Ms. Henson:

On behalf of Clarentis LLC, I am submitting an application for the registration of a "me too" product, ***Ultra-Lyte ™***. This product is substantially similar to EcaFlo Anolyte.

Data Requirements

The generic data is satisfied by citing available sodium hypochlorite data. We have generated our own product chemistry data and efficacy data for submission. The product specific acute toxicity data is supported by using the selective "cite all" method of support. This product qualifies as a A532 submission with a four month review time. This requires a payment of $4,200 and is being paid electronically.

Storage Stability

As indicated in the submitted efficacy testing, an aged sample (60 days old) was used for testing and the data is acceptable. Clarentis LLC is in the process of running stability studies for Ultra-Lyte that will show the product to be stable for one year. We will submit these studies to the Agency as they become available, but request that we be granted full registration and have the Agency make the stability studies a condition of registration as is normal.

This application includes the following documents:

1. One copy of the Application Form (8570-1)
2. One copy of letter of authorization
3. One copy of the Certification with Respect to Data (8570-34)
4. Two copies of the Confidential Statement of Formula (8570-4) (pre-reaction)
5. Two copies of the Confidential Statement of Formula (8570-4) (post-reaction)
6. One copy of the data matrix (8570-35)
7. Five copies of the proposed label
8. Two copies of the transmittal document identifying the submitted data (9 Volumes).
9. Three copies of each of the nine identified studies

If you have any questions about the enclosed submission, please contact me by telephone at 703-922-6677 or by e-mail at Brennis.bob@gmail.com .

Sincerely,

Robert S. Brennis
Agent for,
Clarentis LLC.

Please read instructions on reverse before c leting form. Form Appr OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☒ **Registration**
☐ **Amendment**
☐ **Other**

OPP Identifier Number
XXXXXX

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
86854-R	Wanda Henson	☒ None ☐ Restricted
4. Company/Product (Name) **Clarentis LLC/ Ultra-Lyte ™**	PM# 32	
5. Name and Address of Applicant *(Include ZIP Code)* **Clarentis LLC** 191 NE Boad Haven Road Belfair, WA ***PLEASE SEND ALL CORRESPONDENCE TO "CONTACT POINT" LISTED BELOW*** ☒ *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 82341-1 Product Name EcaFlo Anolyte	

Section - II

☐ Amendment – Explain below.
☐ Resubmission in response to Agency letter dated _____
☐ Notification - Explain below.
☐ Final printed labels in response to Agency letter dated _____
☒ "Me Too" Application
☐ Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This product is substantially similar to EcaFlo Anolyte. The generic data is satisfied by citing available sodium hypochlorite data. The product specific data is satisfied by conducting our own chemistry data and efficacy data and using "cite all" method of support for acute toxicity data. This product qualifies as a A532 submission with a four month review time. Please contact me at 703-922-6677 or at my email address, Brennis.bob@email.com if you need to contact me for any additional information.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes* ☒ No	☐ Yes ☒ No	☐ Yes ☒ No	☐ Metal ☒ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
***Certification must be submitted**	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
☒ Label ☐ Container	1 pint, 1 quart, ½ gallon	☒ On Label ☐ On labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☒ Paper glued ☐ Stenciled ☐ Other _____

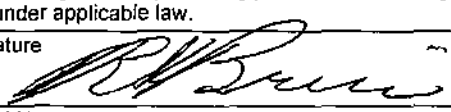
Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application)*

Name	Title	Telephone No (Include Area Code)
Robert S. Brennis, Brennis Consulting Services, 6628 Birchleigh Way, Alexandria, VA 22315	Agent	703-922-6677

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received
	**Agent**	**(Stamped)**
4. Typed Name: Robert S. Brennis	5. Date: *June 22, 2010*	

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete — White- EPA File Copy (original) — Yellow- Applicant Copy

CLARENTIS LLC

March 2, 2010

Ms. Joan Harrigan-Farrelly
Director, Antimicrobial Division (7510P)
Office of Pesticide Programs
Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive (South Building)
Arlington, VA 22202

Dear Ms. Harrigan-Farrelly:

This letter authorizes Mr. Bob Brennis of Brennis Consultants Services LLC, of 6628 Birchleigh Way, Alexandria, VA 22315, to act as agent on behalf of Clarentis LLC on all matters that may come before the U.S. Environmental Protection Agency.

Sincerely,

Duke van Kalken
Clarentis LLC

191 NE Boad Haven Road, Belfair, WA 98528, Tel: (866)-363-7930
E-mail: [redacted]

Personal privacy information

EPA TRANSMITTAL DOCUMENT
CLARENTIS LLC- ULTRA-LYTE

SUBMISSION DATED:	**June 30, 2010**
STUDY SUBMITTER:	**Clarentis LLC**
SUBMITTED IN SUPPORT OF:	**Ultra-Lyte**
EPA REGISTRATION NO.:	**86854-R**
REGULATORY ACTION:	**Application for Pesticide Registration – Old Chemical**
STUDIES SUBMITTED:	**8 Volumes**
STUDY VOLUME 1 of 9:	Chemistry Data for Ultra-Lyte (June 22, 2010) by Robert S. Brennis; 10 pages non-confidential, 12 pages confidential appendix. *US EPA Guidelines 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800* MRID Number:_____
STUDY VOLUME 2 of 9:	Physical and Chemical Characteristics for Ultra-Lyte (June 10, 2010) by David J.Sinning; 7 pages. *US EPA Guidelines 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.7000.830.7100 & 830.7300* MRID Number:_____
STUDY VOLUME 3 of 9:	Determination of Available Chlorine, pH and Hypochlorous Acid Concentration for Ultra-Lyte (April 29, 2010) by Amy S. Jeske,,ATS Labs; 23 pages. US EPA Guidelines 885.1400 MRID Number:_____
STUDY VOLUME 4 of 9:	Efficacy Testing – Pseudomonas aeruginosa (ATCC 15442) Staphylococcus aureus (ATCC 6538) and Salmonella enterica (ATCC 10708) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 29 pages. MRID Number:_____

STUDY VOLUME 5 of 9: Efficacy Testing – Staphylococcus aureus (ATCC 6538) and Salmonella enteric (ATCC 10708) 60 day aged test for Ultra-Lyte (May 24, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number:_____

STUDY VOLUME 6 of 9: Efficacy Testing – Escherichia coli 0157:H7 (ATCC 35150) for Ultra-Lyte (March 19, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number:_____

STUDY VOLUME 7 of 9: Efficacy Testing – Influenza A (H1N1) virus (ATCC VR 99) for Ultra-Lyte (March 29, 2010) by Kelleen Gutzmann,M.S., ATS Labs: 24 pages.

MRID Number:_____

STUDY VOLUME 8 of 9: Efficacy Testing – Listeria monocytogenes (ATCC 19111) for Ultra-Lyte (March 18, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number:_____

STUDY VOLUME 9 of 9: Efficacy Testing – Methicillin Resistant Staphylococcus Aureus – MRSA (ATCC 33592) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number:_____

Company Contact:

Robert S. Brennis
Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
703-922-6677
brennis.bob@gmail.com

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Clarentis LLC, 191 NE Boad Haven Road, Belfair WA 98528	EPA Registration Number/File Symbol 86854-R
Active Ingredient(s) and/or representative test compound(s) hypochlorous acid	Date June 30, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) disinfection of hard surfaces	Product Name Ultra-Lyte

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	June 30, 2010	Robert S.Brennis, Agent for Clarentis LLC

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date June 22, 2010

EPA Reg. No./File Symbol 86854-R

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA 98528

Product
Ultra-Lyte

Ingredient(s):

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550/61-1	Product Identity and Composition		Clarentis LLC	OWN	
830.1600/61-2	Description of the Materials Used to Produce the Product		Clarentis LLC	OWN	
830.1650/61-2	Description of the Manufacturing Process		Clarentis LLC	OWN	
830.1670/61-3	Discussion of Formation of Impurities		Clarentis LLC	OWN	
830.1700/62-1	Preliminary Analysis		Clarentis LLC	OWN	
830.1750/62-2	Certified Limits		Clarentis LLC	OWN	
830.1800/62-3	Enforcement Analytical Method		Clarentis LLC	OWN	
830.6302/63-2	Color		Clarentis LLC	OWN	
830.6303/63-3	Physical State		Clarentis LLC	OWN	
830.6304/63-4	Odor		Clarentis LLC	OWN	
830.7200/63-5	Melting Point		Clarentis LLC	OWN	
830.7220/63-6	Boiling Point		Clarentis LLC	OWN	
830.7300/63-7	Density/Relative Density/Bulk Density		Clarentis LLC	OWN	
830.7840/63-8	Solubility (Column elution/shake flask)		Clarentis LLC	OWN	
830.7950/63-9	Vapor Pressure		Clarentis LLC	OWN	
830.7370/63-10	Dissociation Constant		Clarentis LLC	OWN	
830.7550/7560/7570/63-11	Partition Coefficient		Clarentis LLC	OWN	
830.7000/63-12	pH		Clarentis LLC	OWN	
830.6313/63-13	Stability		Clarentis LLC	OWN	
830.6314/63-14	Oxidation/Reduction: Chemical Compatibility		Clarentis LLC	OWN	
830.6315/63-15	Flammability		Clarentis LLC	OWN	
830.6316/63-16	Explodability		Clarentis LLC	OWN	
830.6317/63-17	Storage Stability		Clarentis LLC	OWN	
830.7100/63-18	Viscosity		Clarentis LLC	OWN	

Signature

Name and Title:
Robert S. Brennis, Agent for AG Technologies

Date
06/22/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

DATA MATRIX

Date June 22, 2010	EPA Reg. No./File Symbol 86854-R	
1. Name and Address of Applicant/Registrant *(Include ZIP Code)* Clarentis LLC 191 NE Boad Haven Road Belfair, WA 98528	Product **Ultra-Lyte**	

Ingredient(s):

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319/63-19	Miscibility		Clarentis LLC	OWN	
830.6320/63-20	Corrosion Characteristics		Clarentis LLC	OWN	
830.6321/63-21	Dielectric Breakdown Voltage		Clarentis LLC	OWN	
885.1400	Analysis of samples		Clarentis LLC	OWN	
Efficacy Data Requirements					
Subdivision G, 91-2	AOAC Use-Dilution Method		Clarentis LLC	OWN	
Toxicology Data Requirements					
870.1100	Acute oral toxicity – rat		Cite all	OLD	
870.1200	Acute dermal toxicity		Cite all	OLD	
870.1300	Acute inhalation toxicity		Cite all	OLD	1
870.2400	Primary eye irritation – rabbit		Cite all	OLD	
870.2500	Primary dermal irritation		Cite all	OLD	
870.2600	Dermal sensitization		Cite all	OLD	

Signature	Name and Title:	Date
	Robert S. Brennis, Agent for AG Technologies	**06/22/10**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date June 22, 2010	EPA Reg. No./File Symbol 86854-R	Page 3 of 3
1. Name and Address of Applicant/Registrant *(Include ZIP Code)* Clarentis LLC 191 NE Boad Haven Road Belfair, WA 98528	Product **Ultra-Lyte**	

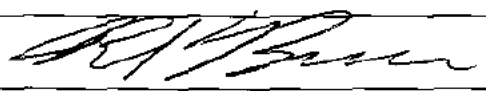
Ingredient(s):

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Generic Data Requirements					
	Please see attached Bibliography This data is OLD and is available for citation. We are citing all of these studies in support of generic data requirements.			OLD	

Key to Notes Codes

1. N/A: Inhalation of solidified silver is not measurable and is no hazard.

The Sodium/Calcium Hypochlorite RED Identified all of the generic data utilized to support the registration of those products. Hypochlorous acid has been supported by this data in previous registrations, and it is appropriate to utilize this data since hypochlorous acid is generally the active ingradient contained within sodium hypochlorite registrations.

Signature	Name and Title:	Date
	Robert S. Brennis, Agent for AG Technologies	06/22/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date June 22, 2010

EPA Reg. No./File Symbol 86854-R

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA 98528

Product
Ultra-Lyte

Ingredient(s):

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
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			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	

Signature	Name and Title:	Date
	Robert S. Brennis, Agent for AG Technologies	06/22/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date June 22, 2010	EPA Reg. No./File Symbol 86854-R	Page 2 of 3
1. Name and Address of Applicant/Registrant *(Include ZIP Code)* Clarentis LLC 191 NE Boad Haven Road Belfair, WA 98528	Product **Ultra-Lyte**	

Ingredient(s):

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
			Clarentis LLC	OWN	
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Signature	Name and Title: Robert S. Brennis, Agent for AG Technologies	Date 06/22/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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Key to Notes Codes

Signature	Name and Title: Robert S. Brennis, Agent for AG Technologies	Date 06/22/10

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Ultra-Lyte™

Aqueous Solution of Sodium Chloride

Ultra-Lyte™ solutions:

- are disinfecting solutions,
- are cost-effective solutions to produce,
- are produced in a simple process by an electrolytic cell,
- can be produced for use in institutional, industrial and commercial applications,
- can be produced with a controlled pH and concentration of Free Available Chlorine (FAC), and
- are produced with low energy costs from water and salt. .

ACTIVE INGREDIENT:
Hypochlorous Acid 0.046%
OTHER INGREDIENTS: 99.954%
TOTAL: 100.000%

Contains **500** ppm Free Available Chlorine (FAC)

KEEP OUT OF REACH OF CHILDREN
CAUTION
See Back Panel for Precautionary Statements

Manufactured by:
Clarentis LLC
191 NE Boad Haven Road
Belfair, WA

Ph: 866-363-7930 Email: info@ultra-lyte.com

EPA Reg. # 086854-R EPA Est. # 086854-WA-001

Ultra-Lyte™ is an activated aqueous solution of sodium chloride produced by passing weak salt brine through an electrolytic cell and temporarily changing the properties of the salt water into a powerful oxidizing agent exhibiting antimicrobial properties. **Ultra-Lyte™** is produced at a near neutral 6.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious specie of chlorine. Hypochlorous acid kills bacteria*.

The properties of **Ultra-Lyte™** can be precisely controlled by manipulating power to the electrolytic cell, brine flow rate through the cell and the conductivity of the brine in the cell. **Ultra-Lyte™** can be applied as a liquid or spray.

Ultra-Lyte™ freezes at 32° F and boils at 212° F. Anolyte is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Ultra-Lyte™** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight.

*Salmonella enterica, Staphylococcus aureus, Staphylococcus aureus MRSA, Escherichia-Coli O157: H7,Listeria Monocytogenes.

DISINFECTION APPLICATIONS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

Hard, Non-Porous Surface Disinfection

To *[Clean and]* Disinfect *[and Deodorize]* Hard, Non-Porous Surfaces: For heavily soiled areas, a preliminary cleaning is required. Apply *[Wipe or Dip]* **Ultra-Lyte™ at 500 ppm** FAC (full strength) to hard, non-porous surfaces with a cloth, wipe, mop or sponge. Treated surfaces must remain wet for 10 minutes. Allow surfaces to air dry. Food contact surfaces such as counters and tables must be rinsed with potable water. Do not use on utensils, glasses or dishes.

Pathogen	Contact Time
Salmonella enterica ATCC 10708	10 minutes
Staphylococcus aureus ATCC 6538	10minutes
Staphylococcus aureus MRSA ATCC 33591	10minutes
Swine Influenza virus (H1N1) ATCC VR 99	10 minutes
Escherichia-Coli O157: H7 ATCC 35150	10 minutes
Listeria Monocytogenes ATCC 19111	10 minutes

Claims:

+ Broad spectrum disinfectant
+ One step cleaner/disinfectant
+ Aids in the reduction of cross-contamination between treated surfaces
+ Assures proper strength, product effectiveness and standardizes technique
+ Formulated for bacteria fighting
+ Bactericide – or – Bactericidal
+ Bathroom disinfectant
+ Kitchen disinfectant
+ Nursery disinfectant
+ Athletic facility disinfectant
+ Cleans and disinfects (insert use site(s) from tables 1-5)
+ Cleans and disinfects hard, non-porous surfaces

+ Cleans, deodorizes and disinfects
+ Deodorizes by killing the germs that cause odors
+ Disinfecting formula
+ Disinfects and deodorizes by killing bacteria and their odors
+ Disinfects hard, non-porous surfaces (throughout the (insert use site(s) from tables 1-5)
+ Easy and convenient disinfecting (throughout the (insert the use site(s) from tables 1-5)
+ Easy one-step cleaning and disinfecting
+ Effective against – or – Kills (insert any organism(s) from table above)
+ Effective against – or – Kills a wide range of bacteria including Staphylococcus aureus MRSA, Salmonella enterica, Pseudomonas aeruginosa
+ Effectively disinfects hard, non-porous, environmental surfaces
+ Eliminates odors at their source; bacteria
+ Eliminates – or – Reduces odors caused by bacteria
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Salmonella enterica
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Staphylococcus aureus MRSA
+ Fight(s) – and/or – Kill(s) – and/or – Effective against Pseudomonas aeruginosa
+ Fight(s) – and/or – Stops – and/or – Prevent(s) cross-contamination on hard, non-porous surfaces (in your (list any use site))
+ Kills bacteria
+ Kills many common bacteria
+ Kills odor-causing bacteria
+ Kills – or – Effective against bacteria
+ Multi-purpose disinfectant
+ One-step cleaner and disinfectant
+ One-step disinfectant cleaner designed for general cleaning and disinfecting hard, non-porous environmental surfaces in health care facilities – or – (insert use site(s) from table 1)
+ Pseudomonocidal
+ Staphylocidal
+ The answer to your disinfection needs
+ The quick-and/or easy and/or –convenient way to disinfect
+ This product controls cross-contamination on most hard, non-porous surfaces
+ Use in public – or – common places where bacteria may be of concern on hard, non-porous surfaces
+ Use where control of the hazards of cross-contamination between treated surfaces is of Prime importance

GENERAL CLAIMS
+ Convenient
+ Easy to handle
+ For general use
+ For use on bathroom surfaces
+ For use on nursery surfaces
+ For use in athletic facilities
+ For use on athletic equipment
+ Will not harm (insert surface material(s) from table 5)
+ Will not harm hard, non-porous inanimate environmental surfaces
+ Will not harm titanium-coated, medical grade stainless steel

Veterinary Uses

Animal Premises: Remove all animals and feed from the premises, vehicles and enclosures. Remove all litter, droppings and manure from the floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks and other feeding and watering appliances. Thoroughly clean all surfaces with soap and/or detergent and rinse with water.
Apply Ultra-Lyte™ (full strength) at 500 ppm FAC. Saturate surfaces with solution for 10 minutes. Immerse all
halters, ropes and other types of equipment used in handling and restraining animals as well as forks, shovels and scrapers used for removing litter and manure. After application, ventilate buildings, coops and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before reuse.

USE SITES
Animal Housing Facilities
Animal Life Science Laboratories
Animal - or -Pet Grooming Facilities
Kennels
Lab Animal Facilities
Livestock – and/or- Poultry Facilities
Pet Areas
Pet Shops – or- Stores
Small Animal Facilities
Veterinary Clinics - or -Facilities
Veterinary - or - Animal Hospitals

SURFACES
Animal equipment automatic feeders
Cages
External surfaces of veterinary equipment
Feed racks
Fountains
Hard, non-porous environmental veterinary surfaces
Pens
Reception counters - or - desks - or – areas
Stalls
Troughs
Veterinary care surfaces
Watering appliances

Food Service Uses:

Food Processing and Service Establishments: Before using this product, food products and packaging materials must be removed from the area or carefully protected.

USE SITES (Food contact surfaces must be rinsed with clean, potable water)
Cafeterias
Commercial - or - Institutional Kitchens
Delis
Fast Food Chains - or - Restaurants
Food Preparation and Processing Areas
Food Processing and Fabrication Areas
Food Service - or - Processing Establishments
Food Serving Areas
Other Food Service Establishments
Restaurants
School Kitchens

SURFACES (Food contact surfaces must be rinsed with clean, potable water)
Surfaces where disinfection is required
Exterior surfaces of Appliances
Exterior surfaces of Dish racks
Drain boards
Exterior surfaces of Food Cases
Exterior surfaces of Food Trays
Exterior surfaces of Freezers
Hoods
Exterior surfaces of Microwaves
Outdoor furniture (excluding wood frames and upholstery)
Exterior surfaces of Ovens
Exterior surfaces of Refrigerators
Salad bar sneeze guards Exterior surfaces of Stoves -or – Stovetops

Miscellaneous / General Uses:

USE SITES
Airplanes
Blood Banks
Boats
Bowling Alleys
Butcher Shops
Chillers
Churches
Colleges
Cooling Towers
Correctional Facilities
Cruise Lines
Day Care Centers
Dormitories

Factories
Funeral Homes
Grocery Stores
Gymnasiums - or - Gyms
Health Club Facilities
Hotels
Industrial Facilities
Laundromats
Laundry Rooms
Lazy Rivers
Locker Rooms
Manufacturing Plants - or - Facilities
Military Installations
Motels
Naval facilities
Oil and gas applications
Oil platforms
Pipelines
Preschool Facilities
Non-food Produce Areas
Public Areas
Public Transportation
Recreational Centers - or - Facilities
Restrooms - or - Restroom Areas
School Buses
Schools
Shelters
Ships
Shipyards
Shower Rooms
Storage Rooms - or - Areas
Supermarkets
Trains
Universities
Wineries
Yachts
Ambulances – or – Emergency Medical Transport Vehicles
Anesthesia Rooms – or – Areas
Assisted Living – or – Full Care Nursing Homes
CAT Laboratories
Central Service Areas
Central Supply Rooms – or – Areas
Home Health Care Settings
Hospital Kitchens
Intensive Care Units – or – ICUs
Laboratories
Physician's – or – Doctor's Offices
Outpatient Clinics
Patient Restrooms
Patient Rooms
Pediatric Examination Rooms – or – Areas

Pharmacies
Plastic mattress covers
Reception counters - or - desks - or - areas
Wash basins
Wheelchairs
Dental - or - Dentist's Offices

SURFACE
Bathroom fixtures
Bath tubs
Behind and under counters
Behind and under sinks
Booster chairs
Cabinets
Ceilings
Ceiling Fans
Cell(ular) - or -wireless - or - mobile - or - digital phones
Chairs
Computer keyboards
Computer monitors
Counters - or - countertops
Cribs
Desks
Diaper - or - infant changing tables
Diaper pails
Dictating equipment surfaces
Doorknobs
Exterior - or - external toilet surfaces
Exterior - or - external urinal surfaces
Faucets
Floors
Garbage - or - trash cans
Grocery store - or - supermarket carts
Hampers
Hand railings
Headsets
Highchairs
Lamps
Linoleum
Other telecommunications equipment surfaces
Playpens
Shelves
Showers - or - shower stalls
Sinks
Stall doors
Tables
Telephones
Tiled Walls
Toilet Rims
Toilet Seats
Towel Dispensers

Toys
Vanity tops - or – vanities

SURFACE MATERIALS
Baked enamel
Chrome
Common hard, non-porous household - or - environmental surfaces
Glazed ceramic tile
Laminated surfaces
Plastic laminate
Glazed porcelain enamel
Stainless steel
Synthetic marble
Vinyl tile
Dental countertops
Dentist - or - dental chairs
Hard, non-porous environmental dental surfaces
Light lens covers
Reception counters – or desks – or areas.
Similar hard, non-porous surfaces except those excluded by the label

Not Recommended For Use On - or - Avoid Contact With:
Aluminum
Brass
Chipped enamel
Clear plastic
Clothes
Copper
Fabrics
Gold
Natural marble
Painted surfaces
Paper surfaces
Natural rubber
Sealed granite
Silver
Unfinished wood
Wood

OIL AND GAS APPLICATIONS – Non-Public Health

Frac Water – For typical water treatment, mix 5 US gallons of Ultra-Lyte™ with 995 US gallons of frac water to 2.5 ppm FAC to mitigate and retard the growth of non-public health microorganisms such as anaerobic bacteria, aerobic bacteria and sulfate reducing bacteria to protect fracturing fluids, polymers and gels.

Sour Wells – For typical well treatment, slug dose 168 US gallons at 500 ppm FAC of Ultra-Lyte™ into the well bore on a daily or weekly basis to control unwanted non-public health microorganisms, reduce hydrogen sulfide gas and restore well integrity.

Produced Waters – For typical produced water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of produced water to 10.5 ppm C, to retard the growth of non-public health microorganisms.

Heater Treaters, Hydrocarbon Storage Facilities & Gas Storage Wells – For typical storage facility treatment, mix 126 gallons Ultra-Lyte™ at 500 ppm FAC into the water phase of the mixed hydrocarbon/water system to retard the growth of non-public health microorganisms, control the formation of hydrogen sulfide and reduce corrosion of the storage tanks.

Water Flood Injection Water – For typical water flood injection water treatment, mix 21 US gallons of Ultra-Lyte™ with 979 US gallons of injection water to 10.5 ppm FAC to retard the growth of non-public health microorganisms and control slime in pipelines.

Oil and Gas Transmission Lines – For typical transmission line treatment, slug dose 420 US gallons at 500 ppm FAC of Ultra-Lyte™ into the transmission line on a daily or weekly basis to control unwanted non-public health microorganisms, such as SRB's, reduce microbiologically influenced corrosion (MIC) and remove the slime and associated sessile bacteria which can degrade pipeline integrity.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in a closed dark plastic container away from direct sunlight. Store container in a cool dry area

Pesticide Disposal: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

Container Disposal: No refillable Container. Do not refill or reuse container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Follow Pesticide Disposal instructions for rinse at a disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times, then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

FIRST AID

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Pesticide Information Center (NPIC) 1- 800-858-7378 for emergency medical treatment information.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present after the first 5 minutes, then continue rinsing eye

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco.

NEW APPLICATIONS

DATE: JUL - 1 2010

FILE NUMBER: 86854-R

FEP (OPPIN ENTRY) LV 7/2/2010
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: _____
(Initial & date)

FILE ROOM: _____
(Initial & date)

✓ **ASSIGN TO PM** 32 **(NO DATA)**

____ **JACKET TO SHELF (DATA)**

PRIA Assessment Form

PRIA Meeting Date_86854-R
W. Henson/Team# 32

Company Name: **CLARENTIS LLC**
Product Name: **ULTRA-LYTE**
Reg/file# **86854-R** Decision **#D-436827** PRIA Code (Months) **A532 (4MONTHS)**
PRIA Code Description: **UNREGISTERED SOURCE OF AI; NEW PRODUCT; CITE-ALL DATA , ETC.**
EPA Receipt Date: **07/01/10** Tentative Due Date (+21 Days) **11/22/10**
Fee Amount **$4,410** Fee Waiver Requested **(Y)** Fee Pd. **(Y)**

Are there currently other registered pesticide products for each active ingredient in this product?
Yes If so, Registration #s _____, _____, _____, _____
Use Pattern _____, _____, _____, _____ _____

Inert Ingredients

Has all inerts been cleared for use in pesticide registration: **YES** NO, If no, list inerts.

Submission Description

Application/Amend. Form **(Y)** New Labels **(Y)** New CSF (Y) Formulator's Exemption Form **(N)** Method of Support Form (Y) **Selective Method** Cite-All Method EP/MUP Data Matrix (Y) TGAI Data Matrix (N)	Ingredient Statement: Hypochlorus Acid……..0.046% A540

List of Uses on the label:. Hard Non-Porous Disinfectant: Veterinary, Food Service, Oil and Gas applications	Are all of the uses on the label approved for each of the actives on the label and source? What are the pesticidal claims? (i.e., **Disinf.,** Sanitizer, Microbiocide/Microbiostat, Virucide Bactericide, Fungicide, Algaecide, Slimicide, Mildewstat

PRIA Assessment Form

PRIA Meeting Date 07/14/2010

Data Submitted? (Y) Data Passed 86-5 Formatting? (Y)

EP/MP Chemistry

EP/MP Acute Tox

EP Efficacy

TGAI F&W_____

Release Rate Study_____

TGAI Fate_____

Submission Deficiencies:

Next Steps:

1.

21-Day Screen Completed by Contractor

21-Day Expires on 7-28-10

Jacket # 86854-R
MRID# 481398

Content Screen: Recommended to [Pass]/Fail

86-5 Review: [Passed]/Failed/NA

Transfer This Jacket to:

WANDA HENSON

JACKETS (Fileroom Document Tracking System)
Requested Jackets Report (New Requests)

12-Jul-2010
1:42 PM
Young, Ollie

Requested by : Henson, Wanda

Barcode : 21142

Agency : EPA Office : OPPTS Program : OPP
Division : AD Branch : RMB2

Requested on 12-Jul-2010 at 01:42 PM

Group Num: 210594

Jacket Barcode	Regulatory Case File #	Vol/Tot	Location	Status
9288252	86854-R	1 / 1	File Rm: 67 / A / 01 / 1	Under Review (02-Jul-2010)

Total # of jackets requested : 1

Completed: OY Date: 7/12 Time: 14^2

Henson, Wanda

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 12, 2010

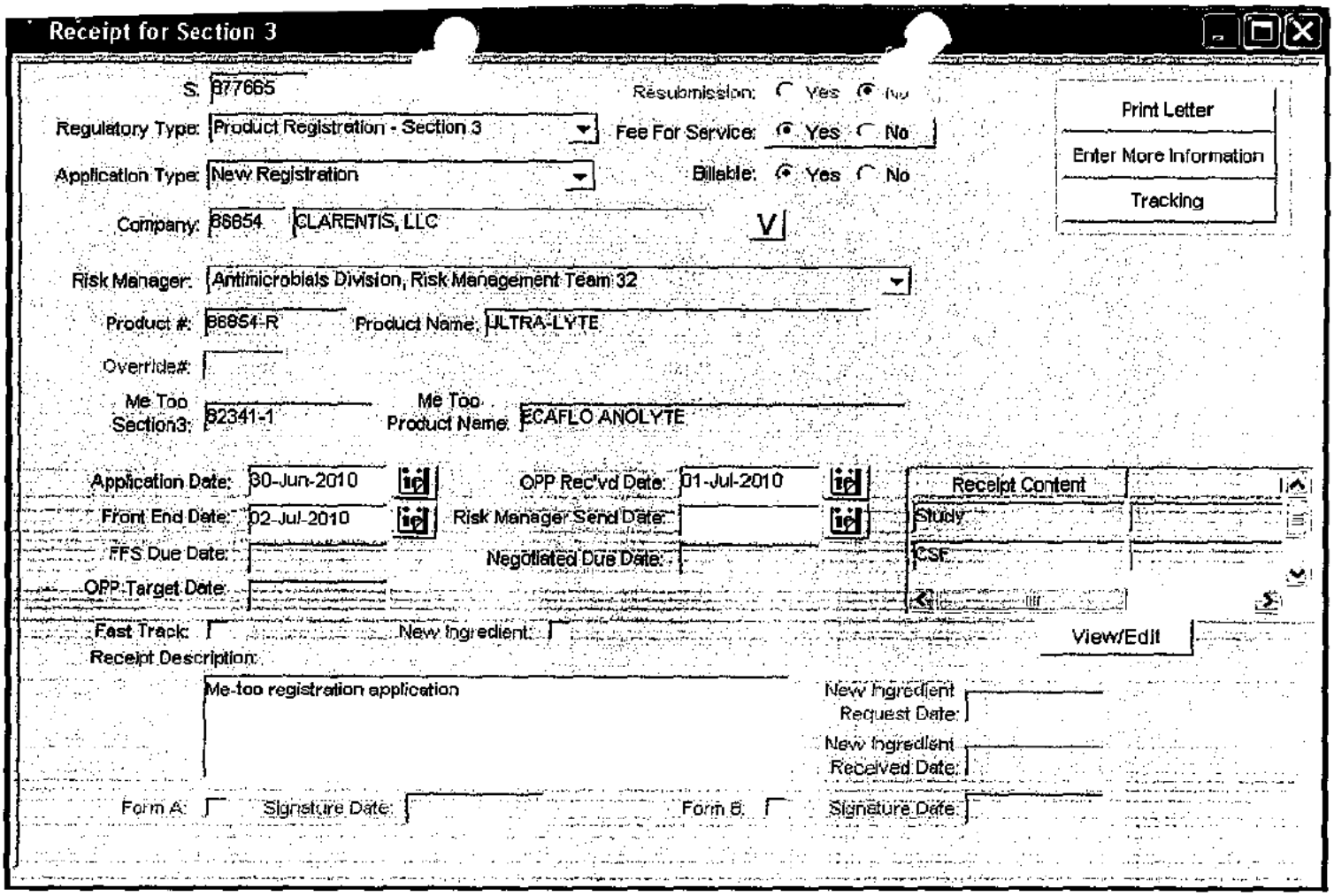
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

CLARENTIS, LLC
191 NE BOARD HAVEN RD
BELFAIR, WA 98528-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-JUL-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 877665
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 86854 CLARENTIS, LLC
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 86854-R
Product Name: ULTRA-LYTE
Override#:
Me Too Section3: 82341-1
Me Too Product Name: ECAFLO ANOLYTE
Application Date: 30-Jun-2010
OPP Rec'vd Date: 01-Jul-2010
Front End Date: 02-Jul-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Me-too registration application
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Brennis Consulting Services LLC

6628 Birchleigh Way, Alexandria, VA 22315
703-922-6677
Brennis.bob@gmail.com

June 30, 2010

U.S. Environmental Protection Agency
Document Processing Desk (7504P)
Room S-4900
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001

ATTENTION: **Wanda Henson**
Product Manager, Team 32

SUBJECT: ***Clarentis LLC***
Ultra-Lyte ^{TM} ***(EPA Appl.No. 86854-R)***
Me Too Registration

Dear Ms. Henson:

On behalf of Clarentis LLC, I am submitting an application for the registration of a "me too" product, ***Ultra-Lyte*** ^{TM}. This product is substantially similar to EcaFlo Anolyte.

Data Requirements

The generic data is satisfied by citing available sodium hypochlorite data. We have generated our own product chemistry data and efficacy data for submission. The product specific acute toxicity data is supported by using the selective "cite all" method of support. This product qualifies as a A532 submission with a four month review time. This requires a payment of $4,200 and is being paid electronically.

Storage Stability

As indicated in the submitted efficacy testing, an aged sample (60 days old) was used for testing and the data is acceptable. Clarentis LLC is in the process of running stability studies for Ultra-Lyte that will show the product to be stable for one year. We will submit these studies to the Agency as they become available, but request that we be granted full registration and have the Agency make the stability studies a condition of registration as is normal.

This application includes the following documents:

1. One copy of the Application Form (8570-1)
2. One copy of letter of authorization
3. One copy of the Certification with Respect to Data (8570-34)
4. Two copies of the Confidential Statement of Formula (8570-4) (pre-reaction)
5. Two copies of the Confidential Statement of Formula (8570-4) (post-reaction)
6. One copy of the data matrix (8570-35)
7. Five copies of the proposed label
8. Two copies of the transmittal document identifying the submitted data (9 Volumes).
9. Three copies of each of the nine identified studies

If you have any questions about the enclosed submission, please contact me by telephone at 703-922-6677 or by e-mail at Brennis.bob@gmail.com .

Sincerely,

Robert S. Brennis
Agent for,
Clarentis LLC.

EPA TRANSMITTAL DOCUMENT
CLARENTIS LLC- ULTRA-LYTE

SUBMISSION DATED:	**June 30, 2010**
STUDY SUBMITTER:	**Clarentis LLC**
SUBMITTED IN SUPPORT OF:	**Ultra-Lyte**
EPA REGISTRATION NO.:	**86854-R**
REGULATORY ACTION:	**Application for Pesticide Registration – Old Chemical**
STUDIES SUBMITTED:	**8 Volumes**
STUDY VOLUME 1 of 9:	Chemistry Data for Ultra-Lyte (June 22, 2010) by Robert S. Brennis; 10 pages non-confidential, 12 pages confidential appendix. *US EPA Guidelines 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800* MRID Number: **48139801**
STUDY VOLUME 2 of 9:	Physical and Chemical Characteristics for Ultra-Lyte (June 10, 2010) by David J.Sinning; 7 pages. *US EPA Guidelines 830.6302, 830.6303, 830.6304, 830.6314, 830.6315, 830.6316, 830.7000.830.7100 & 830.7300* MRID Number: **48139802**
STUDY VOLUME 3 of 9:	Determination of Available Chlorine, pH and Hypochlorous Acid Concentration for Ultra-Lyte (April 29, 2010) by Amy S. Jeske,,ATS Labs; 23 pages. US EPA Guidelines 885.1400 MRID Number: **48139803**
STUDY VOLUME 4 of 9:	Efficacy Testing – Pseudomonas aeruginosa (ATCC 15442) Staphylococcus aureus (ATCC 6538) and Salmonella enterica (ATCC 10708) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 25 pages. MRID Number: **48139804**

STUDY VOLUME 5 of 9: Efficacy Testing – Staphylococcus aureus (ATCC 6538) and Salmonella enteric (ATCC 10708) 60 day aged test for Ultra-Lyte (May 24, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139805**

STUDY VOLUME 6 of 9: Efficacy Testing – Escherichia coli 0157:H7 (ATCC 35150) for Ultra-Lyte (March 19, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139806**

STUDY VOLUME 7 of 9: Efficacy Testing – Influenza A (H1N1) virus (ATCC VR 99) for Ultra-Lyte (March 29, 2010) by Kelleen Gutzmann,M.S., ATS Labs: 24 pages.

MRID Number: **48139807**

STUDY VOLUME 8 of 9: Efficacy Testing – Listeria monocytogenes (ATCC 19111) for Ultra-Lyte (March 18, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139808**

STUDY VOLUME 9 of 9: Efficacy Testing – Methicillin Resistant Staphylococcus Aureus – MRSA (ATCC 33592) for Ultra-Lyte (March 22, 2010) by Joshua Luedtke, M.S.,ATS Labs: 23 pages.

MRID Number: **48139809**

Company Contact:

Robert S. Brennis
Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
703-922-6677
brennis.bob@gmail.com

Memorandum

Date: 7/12/10

To: PM 32, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

EPA

ADMINISTRATIVE NO(S).: 86854-R

PM: 32

CHEMICAL NO.:

The jacket for this action can be requested through the JACKETS system.

UN. ED STATES ENVIRONMENTAL PROTEC. ON AGENCY
WASHINGTON, D.C. 20460

File copy

July 16, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-436827
EPA File Symbol or Registration Number: 86854-R
Product Name: ULTRA-LYTE
EPA Receipt Date: 01-Jul-2010
EPA Company Number: 86854
Company Name: CLARENTIS, LLC

DAVID WALTERICK
CLARENTIS, LLC
191 NE BOARD HAVEN RD
BELFAIR, WA 98528-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as A532 has been reclassifie as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 7-7-10 (RELEASED DATE)

Experts In-Processing Signature: B. Ro Date 7-8-10 Fee Paid: Yes ✓

Division management contacted on issues No _____ Yes _____ Date _____

EPA Reg. Number: 86854-R	EPA Receipt Date: 7-7-10

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)	X		
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A) — yes: X; no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: ; no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X; no:			
	b) Cite-All (Fee category experts use) — yes: ; no:			
	c) Applicant owns all data (Fee category experts use) — yes: ; no:			
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)	X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

A.I. : water only

Passed 86-5 Review. M2ID 481398 -JD

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Robert Brennis
Phone #: 703-922-6677
Email: Brennis.bob@gmail.com

First Call/Initials:	**Second Call/Initials:**
Date: 7/12	**Date:**
Time: 12:09 PM	**Time:**

This is Jennifer Drobish **, EPA contractor.**

I'm calling regarding your submission in support of
86854-R Ultra-Lyte .

We have found the following deficiencies regarding:
PR Notice 86.5: Yes or No
Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: (Yes) or No

Missing external copy of Data Matrix

These deficiencies have been approved by EPA.
The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:
If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.

RE: Application for Registration of Ultra-Lyte
Bob Brennis to: Jennifer Drobish 07/12/2010 12:26 PM

Please find attached the public data matrix.

Bob Brennis

Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
703-922-6677 office
[redacted] cell

Personal privacy information

-----Original Message-----
From: Drobish.Jennifer@epamail.epa.gov
[mailto:Drobish.Jennifer@epamail.epa.gov]
Sent: Monday, July 12, 2010 12:13 PM
To: brennis.bob@gmail.com
Cc: Nair.Sree@epamail.epa.gov
Subject: Application for Registration of Ultra-Lyte

Hi Mr. Brennis

This is Jennifer Drobish, EPA contractor. I'm writing to follow up on the message I left for you regarding the subject registration. The application package is miss the external copy of the Data Matrix (EPA form8570-35). That form can either be faxed to me at 703-305-5060/Attn: Jennifer Drobish or emailed to me at drobish.jennifer@epa.gov

Thank you
Jennifer Drobish
EPA Contractor
703-305-1671

No virus found in this incoming message.
Checked by AVG - www.avg.com
Version: 9.0.830 / Virus Database: 271.1.1/2993 - Release Date: 07/12/10 02:36:00

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 7, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-436827
EPA File Symbol or Registration Number: 86854-R
Product Name: ULTRA-LYTE
EPA Receipt Date: 01-Jul-2010
EPA Company Number: 86854
Company Name: CLARENTIS, LLC

BRENNIS CONSULTING SERVICES LLC
AGENT FOR: CLARENTIS, LLC
6628 BIRCHLEIGH WAY
ALEXANDRIA, VA 22315

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A532

UNREGISTERED SOURCE OF ACTIVE INGREDIENT;NEW PRODUCT;CITE-ALL DATA CITATION EXCEPT FOR PRODUCT CHEMISTRY;IDENTICAL OR SUBSTANTIALLY SIMILAR IN COMPOSITION AND USE TO A REGISTERED PRODUCT;PRODUCT CHEMISTRY DATA SUBMITTED;REGISTERED ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6427.

Sincerely, Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

FW: Pay.Gov Payment Confirmation
Bob Brennis to: Teresa Downs, Teresa Downs 07/07/2010 10:51 AM
Cc: "'David Walterick'", "'Duke van Kalken'"

Teresa -

Below is the confirmation of payment for Clarentis (Ultra-Lyte, EPA Appl. 86854-R). Let me know if you require anything additional.

Thank you for your help.

Bob Brennis

Brennis Consulting Services LLC
6628 Birchleigh Way
Alexandria, VA 22315
703-922-6677 office
[redacted] cell

Personal privacy information

-----Original Message-----
From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]
Sent: Tuesday, July 06, 2010 10:37 AM
To: walterickd@wwdb.org
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 251341ME
Agency Tracking ID: 74125018831

Account Holder Name: Clarentis LLC
Transaction Type: Sale
Transaction Amount: $4,410.00
Billing Address: 191 NE Boad Haven Rd.
City: Belfair
State/Province: WA
Zip/Postal Code: 98528
Country: USA
Card Type: Master Card
Card Number: **********1707
Transaction Date: Jul 6, 2010 1:36:35 PM

Decision Number:
Registration Number: 86854-R
Company Name: Clarentis LLC
Company Number: 86854
Action Code: A532

RESPONSE REQUIRED BY 7/15/10: Proof of PRIA fee payment required for application to register Ultra-Lyte (EPA file symbol 86854-R)

Teresa Downs to: Robert Brennis 07/06/2010 10:19 AM

Good morning, Bob,

The Antimicrobial Division's PRIA team has identified the above action as subject to action code A532. Please email me a pay.gov receipt or a copy of a check in the amount of **$4,410** as proof of fee payment.

Section 33(B)(2(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Renewal Act, provides that the fee is due upon submission of the application. We received this action on 7/1/10. If proof of fee payment is not received by COB on 7/15/10, then we will reject this action for non-payment of the PRIA fee and send you an invoice for $1,103. The Agency is required to collect a minimum of 25% of the applicable fee even if an application is rejected. If you do not pay the invoice by the date specified therein, then the fees will be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

If you have questions about the assignment of the above action code, please contact ShaRon Carlisle at (703)308-6427 or carlisle.sharon@epa.gov

Teresa Downs
Information Services Branch
Office of Pesticide Programs
U.S. Environmental Protection Agency
phone: (703)305-5363
fax: (703)305-7670
www.epa.gov/pesticides

Released

~~ON HOLD~~

Pending receipt of certification of PRIA fee payment

Date placed on hold: 7/6/10

Date released: 7/7/10

Receipt: S- 877606

File Symbol/Reg. #: 87584-R

Registrant contact information:

Name: Bob Brennis

Phone #/Email address: brennis.bob@gmail.com

Notes: No proof of fee payment, amt. mentioned is incorrect

7/6/10 Sent email

Information Services Branch point of contact: Teresa Downs, S-6922, (703)305-5363

Fee for Service

{877665S~

This package includes the following

- (•) New Registration
- ( ) Amendment

[x] Studies? [ ] Fee Waiver?

[ ] volpay % Reduction: ___

for Division

- (•) AD
- ( ) BPPD
- ( ) RD

Risk Mgr. 32

Receipt No. S- 877665

EPA File Symbol/Reg. No. 86854-R

Pin-Punch Date: 7/1/2010

[ ] This item is NOT subject to FFS action.

Action Code:

Requested: A532

Granted: A532

Amount Due: $ 4410

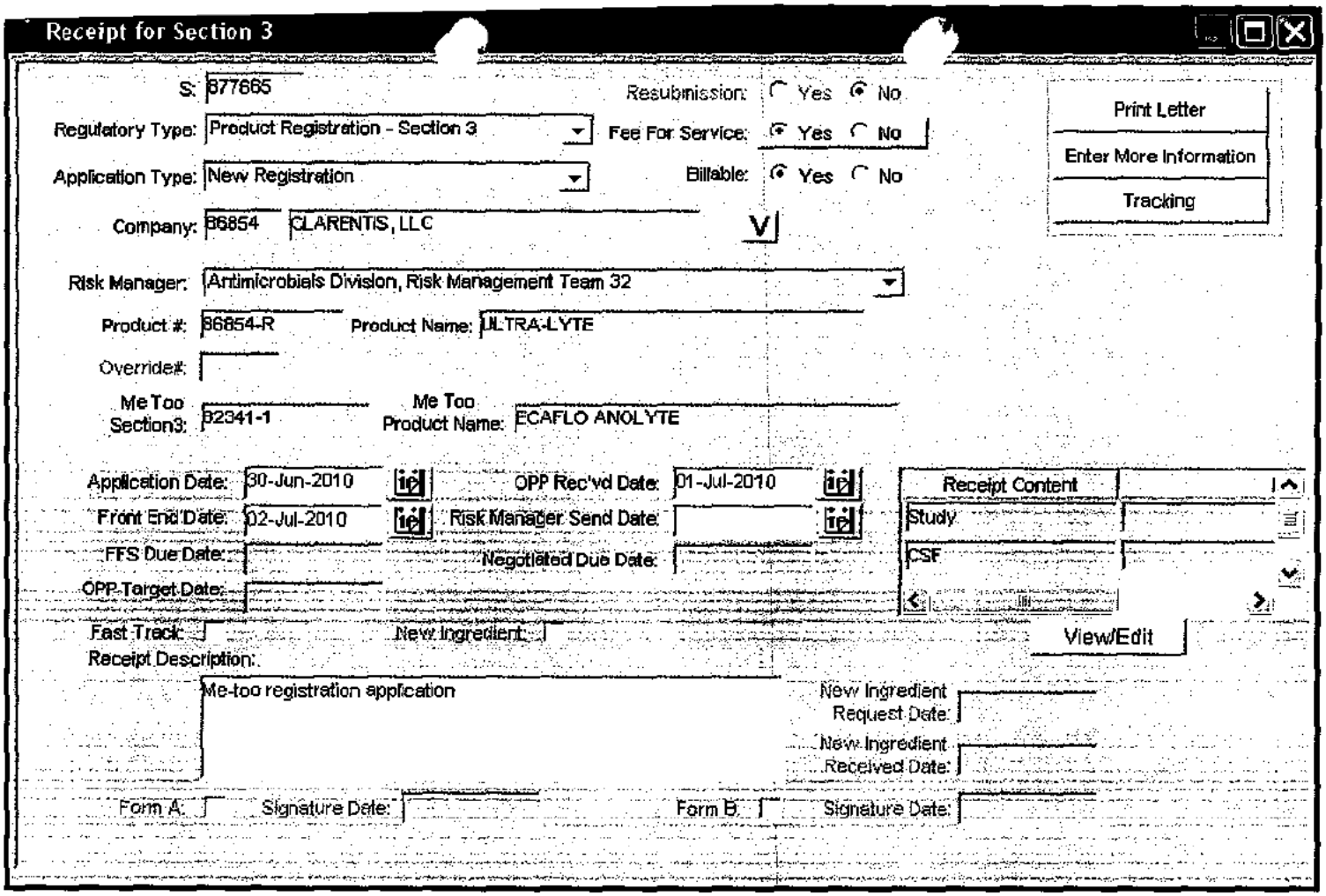
Parent/Child Decisions:

[x] Inert Cleared for Intended Use [x] Uncleared Inert in Product

Reviewer: Team 2 Date: 7/2/10

Remarks:

Is Prod. Chemistry required?


Receipt for Section 3
S: 877665
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 86854 CLARENTIS, LLC
Risk Manager: Antimicrobials Division, Risk Management Team 32
Product #: 86854-R
Product Name: ULTRA-LYTE
Override#:
Me Too Section3: 92341-1
Me Too Product Name: ECAFLO ANOLYTE
Application Date: 30-Jun-2010
OPP Rec'vd Date: 01-Jul-2010
Front End Date: 02-Jul-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Me-too registration application
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: JUL - 1 2010	EPA Reg. Number: 86854-R

	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?		X	
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?	?	X	
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**		X	